IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation, *et al*. Defendants.	)	Civil Action No. 04-12457 PBS

MEMORANDUM IN SUPPORT OF DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S MOTION *IN LIMINE* TO PRECLUDE DR. BROOKSTEIN FROM TESTIFYING AS AN EXPERT AT TRIAL REGARDING THE EFFECT OF COATING ON FIBERWIRE'S PROPERTIES OR PERFORMANCE

Dated: July 13, 2007

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I. INTRODUCTION

As the Court is aware, the parties agreed to limit the issues at the upcoming trial, scheduled to begin August 6, 2007, to whether defendant Arthrex, Inc.'s ("Arthrex's") FiberWire suture products infringe the asserted claims of U.S. Patent No. 5,314,446 ("the '446 Patent"). The principle issue in the case is whether the coating added to FiberWire materially affects the basic and novel properties of the invention,[1] defined by the Court as:

> The court defined the basic and novel properties of the invention as:
>
> (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.

Ex. 1 at 18-19. Defendants Arthrex and Pearsalls file this motion because discovery revealed that Dr. Brookstein, one of Plaintiff DePuy Mitek's experts, is wholly unqualified to testify on this subject.

In two separate expert reports, Dr. Brookstein opined that the coating added to FiberWire sutures does not materially affect the basic and novel properties of the invention.[2] Yet when he was asked at his deposition to confirm that it is generally known coating is added to multifilament sutures in order to improve the tactile smoothness and knot tie-down of such sutures -- undisputed facts that are universally-known throughout the suture industry -- Dr.

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[1] Defendants Arthrex and Pearsalls, Ltd. ("Pearsalls") are asserting other defenses in this case. Defendants also claim that its FiberWire suture does not infringe the '446 Patent because of the adhesive applied to the suture during the tipping process, which Defendants claim materially affects the pliability and/or handleability of the suture. Defendants also claim non-infringement under the reverse doctrine of equivalents. Further, Pearsalls claims that it does not contribute to the alleged infringement. While Defendants plan to raise these issues at trial, they are not relevant for purposes of this motion *in limine* because Dr. Brookstein expressed no opinions on these issues.

[2] Dr. Brookstein expresses this opinion in both the Rebuttal Expert Report of Dr. David Brookstein (Ex. 2) at 2 and 9-31; and also in the Amended Supplemental Expert Report of Dr. David Brookstein (Ex. 3) at 21.

Brookstein testified that he had never heard any of that before and that he had no opinions on those subjects. Of course, that is understandable since Dr. Brookstein, while a qualified expert on braiding of textile materials, has absolutely no expertise or experience on coating suture. In fact, only once in his entire professional life was Dr. Brookstein involved in designing and developing sutures. And on that one project, Dr. Brookstein's role was limited to the braiding operation; he could not testify that the one suture project involved coating.

For these reasons, and the reasons explained herein, Dr. Brookstein is not qualified, under Fed. R. Evid. 702, to give expert testimony on the subject of whether the coating added to FiberWire suture has *any* effect on the properties of the suture. Accordingly, defendants move *in limine* to preclude Dr. Brookstein from offering any such opinions at trial.

II. THE LAW OF QUALIFYING EXPERTS

In *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993), the Supreme Court, "impose[d] on a federal trial judge the duty to act as a 'gatekeeper,' guarding the fact-finding process against infiltration by 'expertise that is fausse and science that is junky.'" *Polaino v. Bayer Corp.*, 122 F.Supp.2d 63, 66 (D. Mass. Nov. 13, 2000) (quoting Supreme Court in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999)).

"Two gateposts frame the exercise of a judge's discretion to admit or exclude expert testimony. First, the proffered expert must be shown to be sufficiently qualified by 'knowledge, skill, experience, training, or education.'" *Id*. (citing Fed. R. Evid. 702). "Stated more simply, the trial judge must first determine that the proffered expert is in fact qualified by training or experience to render an opinion." *Id.*[3] Further, "an expert's qualifications *must* relate to the subject matter of the proposed testimony" and "experience that has been gained solely through

[3] The second gatepost requires judges to "'ensure that any and all scientific testimony or evidence admitted is not only relevant, but [also] reliable.'" *Id*. (quoting *Daubert*, 509 U.S. at 589). This second gatepost function is not raised by this motion.

litigation is generally accorded little weight." *Watson v. Electrolux Professional Outdoor Prods., Inc.*, 2006 WL 2246416 at *3 (D. Mass. Aug. 4, 2006) (Ex. 4) (emphasis added).

III. DR. BROOKSTEIN IS NOT QUALIFIED AS AN EXPERT ON COATING'S EFFECT ON SUTURE PROPERTIES OR PERFORMANCE AND SHOULD BE PRECLUDED FROM OFFERING ANY SUCH OPINIONS AT TRIAL

While Dr. Brookstein may be qualified to testify as an expert in the field of braiding textiles, one thing is for certain, he is absolutely unqualified -- much less does he have *any* level of expertise -- to testify regarding coating's effect on the properties or performance of a multifilament suture.

Although he purported to render opinions in his two expert reports regarding coating's effect on the properties of FiberWire suture (Exs. 2 and 3), at his deposition, Dr. Brookstein repeatedly testified that he had no knowledge about coating's effect, in general, on a suture's tactile smoothness, knot tie-down and pliability properties.

Specifically, with respect to *tactile smoothness*, Dr. Brookstein testified as follows:

> Q: Is it correct that it is generally known in the suture art that coating a multifilament suture improves the tactile smoothness of the suture?
>
> A: I haven't seen anything that says that.
>
> Q: You don't have an opinion one way or the other?
>
> A: I have no opinion on that.

Ex. 5 at 166:15-167:1.

With regard to *knot tie-down*, Dr. Brookstein testified as follows:

> Q: Do you agree that it is generally known in the suture art that coating a multifilament suture improves that knot tie-down performance of that suture?
>
> A: I've seen no evidence where that's discussed.

Ex. 5 at 167:24:168:2.

And, with regard to *pliability*, Dr. Brookstein testified as follows:

Q: Do you know whether it is generally known in the suture art that coating a multifilament suture improves the pliability of that suture?

A: Yeah, I've seen nothing like that. I can't judge that.

Ex. 5 at 167:2-9.

What makes Dr. Brookstein's testimony all the more shocking is the fact that he was not being questioned about some abstract theories that only a few in the suture industry might hold. Rather, he was being asked -- as Mitek's purported suture coating expert -- merely to confirm the universally-known fact that coatings are applied to multifilament sutures so as to improve their tactile smoothness and their knot tie-down. As the Court is well aware, even *DePuy Mitek* does not dispute this evidence. Yet, this all seemed foreign to Dr. Brookstein.

In fact, the questions Dr. Brookstein was being asked at his deposition were framed from Ethicon's own patents -- one more than 20 years-old and others naming one of the inventors from the '446 Patent -- that were stating these well-known principles. Ex. 6 at Abstract, col. 1, ll. 14-18; Ex. 7 at col. 1, ll. 11-15; Ex. 8 at col. 1, ll. 8-12.

These same Ethicon patents were shown to Dr. Brookstein at his deposition (as Defendants Exhibits 202, 203 and 204) and he was told that they were owned by Ethicon -- the sister company of Mitek, who hired him as an expert in this case. Yet, when asked if he had any reason to doubt what Ethicon was saying in these patents about coating's effect on multifilament sutures, he had only the following to say:

Q: Do you have any reason to believe that Ethicon, Inc. would be providing statements in the – in its patent that it didn't believe to be true?

A: I have no idea how Ethicon's business practices are. How would I know?

Ex. 5 at 176:14-23.

What is more, those same three Ethicon patents were attached as exhibits to Dr. Mukherjee's (*i.e.*, Defendants' suture expert) expert report concerning non-infringement[4] -- the same report to which Dr. Brookstein was purportedly responding in his rebuttal expert report.[5] Yet he admitted he had never seen any of those patents before, even though he had an opportunity to review them since they were attached to Dr. Mukherjee's expert report. Ex. 5 at 170:2-5 and 174:17-21 (with regard to Defendants' Deposition Exhibit 202); Ex. 5 at 177:14-178:5 (with regard to Defendants' Deposition Exhibit 203); Ex. 5 at 182:11-183:1 (with regard to Defendants' Deposition Exhibit 204).

Not only did Dr. Brookstein ignore the suture industry patents that were attached to Dr. Mukherjee's responsive expert report, but he also admitted he made no effort to review any other patents in the suture field. Specifically, Dr. Brookstein testified as follows:

> Q: Did you ever try to review the patent literature on coating of sutures in connection with rendering opinions in this case?
>
> A: I don't recall looking at other patents, no.

Ex. 5 at 170: 6-10.

Moreover, when Dr. Brookstein was asked about his own personal experience with respect to suture coatings, he testified as follows:

> Q: Do you recall whether you have any experience with respect to what coating -- how coating impacts on suture properties?
>
> A: Well, I've looked at the Gitis report and tried to –
>
> Q: I'm sorry, prior to your work in this case.
>
> A: *Not prior to the work in this case*.

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[4] Specifically, these three Ethicon patents were attached as Exhibits 9-11 of the Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 And Other Matters dated March 24, 2006.

[5] His rebuttal expert report being the Rebuttal Expert Report of Dr. David Brookstein dated April 13, 2006.

Q: Okay, would it be correct to say that what you've learned about coating and its impact on suture properties is in conjunction with your work on this case?

A: *That would be proper to say that, yes.*

Ex. 5 at 165:15-166:3 (emphasis added). Thus, not only did Dr. Brookstein avoid reviewing any literature addressing coating's well-known effects on suture properties, but he admitted that the *only* experience he has with coating's effect on suture properties comes from this case, and more specifically, from *Defendants'* expert. But, this court has already stated that "experience that has been gained solely through litigation is generally accorded little weight." *Watson,* 2006 WL 2246416 (Ex. 4) at *3.

Dr. Brookstein eventually explained *why* he was so content with staying ignorant with regard to coating's effects on multifilament sutures. He simply does not believe that the '446 Patent has anything to do with coating. Dr. Brookstein explained this when he testified about why he never inquired as to whether the Mitek or Ethicon ever did any tests on coating's effect on FiberWire. Specifically, Dr. Brookstein testified as follows:

Q; Do you know whether DePuy Mitek or Ethicon has ever done any tests on the effect of coating on the FiberWire suture?

A: I have no way of knowing that.

Q: Did you ever ask whether any such tests were done?

A: No.

. . . . . .

Q: So, in your opinion, if Ethicon has tests talking about the effect of coating on the FiberWire product, that would be unimportant to you?

A: If Ethicon has?

Q: Yes, sir, or DePuy Mitek.

A: In the context of this patent?

Q: In the context – yeah, for the purposes of rendering your opinions in this case.

A: For the purpose of rending this opinion –

Q: Any of the opinions in this case.

A: --on this case associated with the '446. It means nothing to me about the coating because the coating is not what this patent is about.

Ex. 5 at 201:6-204:5.

Dr. Brookstein maintained his know-nothing theme when he was asked about FiberWire suture, and more specifically, about an Arthrex document that describes the effect of the silicone coating applied to FiberWire (Ex. 9), Dr. Brookstein testified as follows:

Q: Do you see in the first paragraph about two-thirds of the way down the sentence that says, The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue?

A: I see that sentence.

Q: Do you have any reason to disagree with that sentence?

A: I have not analyzed -- I have not measured FiberWire -- I have not measured FiberWire properties to see how the coating acts.

Ex. 5 at 198:17-199:2.

As mentioned above, Dr. Brookstein's expertise lies with the braiding of textiles -- not with regard to coating's effect on the properties of multifilament sutures. When asked about the *single* suture project in his entire professional life on which he actually worked, Dr. Brookstein testified that he assumed the reason why he was brought in was due to his expertise in braiding. Ex. 5 at 43:10-15. In fact, coating is so far from Dr. Brookstein's area of expertise that he could not even recall whether that one suture he worked on had a coating. Ex. 5 at 164:16-165:4.

As this Court has previously stated, "an expert's qualifications must relate to the subject matter of the proposed testimony." *Watson*, 2006 WL 2246416 (Ex. 4) at *3. Dr.

Brookstein could not demonstrate any more clearly that he does *not* know the first thing about coating's effect on the properties or performance of multifilament sutures. Yet that is precisely the subject matter of both the opinions he expressed in this case and also to which he intends to testify at trial.[6]

Dr. Brookstein's revealing deposition testimony is more than enough reason to exclude him from testifying at trial on coating's effect on the properties or performance of multifilament sutures. In *Polaino,* the court cited the purported expert's deposition testimony as a basis for excluding his testimony at trial. *Polaino*, 122 F.Supp.2d at 69. The same result should follow.

The Supreme Court has instructed that the trial judge has a duty to protect the jury from "experts" such as Dr. Brookstein – experts that have absolutely no prior knowledge about a subject on which they freely offer expert opinions; "experts" that go out of their way to avoid an education on the very subject matter on which they are opining; and "experts" whose only exposure to the subject matter on which they are opining comes from the very litigation for which they were hired.

Defendants reiterate that they do not object to Dr. Brookstein testifying at trial with regard to textile braiding, an area within his expertise. But Defendants do object to Dr. Brookstein being permitted to testify at trial regarding coating's effect on the properties or

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[6] DePuy Mitek may respond to this motion by stating that it was Dr. Brookstein, and not Defendants' expert Dr. Mukherjee, that actually visited the Pearsalls facility in England where he watched how the coating is applied to FiberWire suture. This is a failed argument, however, since just as Dr. Brookstein watched the coating being applied, so did all of the attorneys who were there. That one visit does not qualify either the attorneys or Dr. Brookstein as an expert on coating's effect on the properties of multifilament sutures. Moreover, the law is crystal clear that experience gained in the course of litigation cannot qualify you as an expert. *Watson*, 2006 WL 224641 (Ex. 4) at *3. In contrast to Dr. Brookstein, Dr. Mukherjee spent decades of his professional life in the manufacture of surgical sutures. No amount of spin by DePuy Mitek regarding a trip to rural England can change that fact.

performance of FiberWire or any other multifilament suture after he so clearly demonstrated that he is not "qualified as an expert" under Fed. R. Evid. 702.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion should be granted.

Dated: July 13, 2007

Respectfully submitted,

By: **/s/Charles W. Saber**

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Arthrex, Inc. and Pearsalls Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S MOTION *IN LIMINE* TO PRECLUDE DR. BROOKSTEIN FROM TESTIFYING AS AN EXPERT AT TRIAL REGARDING THE EFFECT OF COATING ON FIBERWIRE'S PLIABILITY AND/OR HANDLEABILITY , and MEMORANDUM in support thereof, were served, via the Court's email notification system on the following counsel for Plaintiff on the 13th day of July 2007:

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Exhibit 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 04-12457-PBS
ARTHREX, INC. and PEARSALLS LTD. Defendants.	)	

MEMORANDUM AND ORDER

January 31, 2007

Saris, U.S.D.J.

INTRODUCTION

Plaintiff DePuy Mitek, which specializes in the manufacture of surgical devices, alleges that Arthrex, Inc., and Pearsalls Ltd. (collectively "Arthrex"), two of Plaintiff's competitors, have infringed U.S. Patent No. 5,314,446 ("the '446 Patent"). Broadly, the '446 patent protects a braided surgical suture with two multi-filament yarns made from different materials. Beyond this definition, though, the parties disagree as to two key terms in the '446 Patent.

DePuy Mitek and Arthrex have moved for summary judgment on the issue of infringement. After a Markman hearing, the Court defines the two contested patent terms and **DENIES** without prejudice Plaintiff's motion for summary judgment of infringement and Defendants' motion for summary judgment of noninfringement.

FACTUAL BACKGROUND

1. The '446 Patent

The patent,[1] also known as the Hunter Patent, protects a sterilized heterogeneous braided suture. Claim One recites:

> A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and
>
> a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and
>
> b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and
>
> c) optionally a core

'446 Patent col.8-9 ll.63-68, 1-9 (emphasis added). The construction of the underlined terms "consisting essentially of" and "PE" are disputed.

2. Procedural History

On November 19, 2004, DePuy Mitek filed this "suture suit" against Arthrex, claiming that two of Arthrex's products - FiberWire® and TigerWire® - infringe the '446 patent. It amended its complaint on September 9, 2005 to include similar allegations

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[1]On May 24, 1994, the United States Patent and Trademark Office issued the '446 Patent, which was assigned to to Ethicon, Inc., a New Jersey based medical device company wholly owned by Johnson & Johnson. On August 9, 2004, Ethicon transferred its interest in the '446 Patent to DePuy Mitek, another Johnson & Johnson subsidiary. DePuy Mitek currently owns this patent.

against Pearsalls, the company responsible for manufacturing the materials and braids that ultimately become part of the FiberWire and TigerWire sutures sold by Arthrex.

FiberWire is a surgical suture that is formed by braiding together yarns of ultra high molecular weight polyethylene ("UHMWPE") and yarns of polyethylene terephthalate ("PET"). These yarns are braided together so that they are in direct intertwining contact with one another. The Defendants also add a silicone coating to the braided suture, which, they argue, significantly improves the handleability and pliability of the device. TigerWire, unlike FiberWire, is composed of a UHMWPE filament and a yarn of nylon. In all other material aspects, however, TigerWire is identical to FiberWire.[2] As such, this Court will refer to these products collectively as "FiberWire."

The Defendants argue that they do not infringe the patent because the UHMWPE utilized in the FiberWire suture is different from the "general purpose" PE described in Claim One. Second, the Defendants submit that the coating on the FiberWire suture removes the product from the scope of Claim One of the '446 Patent.

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[2]As part of a motion to strike, the Defendants raise the possibility that TigerWire may be sufficiently dissimilar from FiberWire so as to warrant a separate examination of the two sutures. However, the differences between the two are not relevant to this opinion, although these distinctions may ultimately prove important.

DISCUSSION

1. Claim Construction

In construing a claim, this Court must first "look to the words of the claims themselves...to define the scope of the patented invention." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citation omitted). The language of the patent claims should be given first priority in the patent construction process because "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

Terms in the patent claims "are generally given their ordinary and customary meaning." Vitronics, 90 F.3d at 1582. The Federal Circuit has held that "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313 (citations omitted). This "inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." Id.

Despite the primary role that the plain meaning of the claim language plays in divining the subject matter of a patent, the

Federal Circuit has held that the plain language of the patents is best understood when viewed "in the context of the entire patent, including the specification." Id. Courts must examine the terms of the claim in light of the entire patent because

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention - the inventor's lexicography - must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, *viz.*, the patent specification and the prosecution history.

Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

Therefore, in interpreting a given claim term, the Court should first look to all intrinsic evidence. First, the Court consults the claims themselves, which "provide substantial guidance as to the meaning of particular claim terms." Phillips, 415 F.3d at 1314 (quoting Vitronics, 90 F.3d at 1582). By examining "the context of the surrounding words of the [disputed] claim," an interpreter may properly comprehend and "determin[e] the ordinary and customary meaning of those [disputed] terms." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).

Second, the Court must properly weigh the "specification

that concludes with the claims." Phillips, 415 F.3d at 1315. Therefore, the claims of a patent "must be read in view of the specification, of which they are a part." Id. (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995)). As a consequence, the Federal Circuit has opined: "The specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Thus, the specifications should guide this Court in its study of the evidence presented by the patent.

Finally, as part of this intrinsic evidence analysis, the Court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. "Like the specification," the Federal Circuit has suggested that "the prosecution history provides evidence of how the PTO and the inventor understood the patent." Phillips, 415 F.3d at 1317. Nevertheless, the Court has cautioned that prosecution histories, unlike other forms of intrinsic evidence, "often lack[] the clarity of the specification and thus [are] less useful for claim construction purposes." Id. (citations omitted).

In contrast to the intrinsic evidence analysis endorsed by the Court in Phillips, extrinsic evidence, "consist[ing] of all evidence external to the patent and prosecution history,

including expert and inventor testimony, dictionaries, and learned treatises," is less favored in the claim construction analysis. Markman, 52 F.3d at 980 (citing Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 546 (1870)). Although the Court has expressly "authorized district courts to rely on extrinsic evidence," Phillips, 415 F.3d at 1317, the Federal Court warned that such exogenous evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)). Therefore, the Court has resolved to "emphasize[] the importance of intrinsic evidence in claim construction" because "extrinsic evidence...is unlikely to result in a reliable interpretation of patent claim scope." Phillips, 415 F.3d at 1319.

A. Meaning of "PE"

The parties dispute the proper scope of the term "PE" in the context of the '446 patent. Plaintiff contends that PE includes any polymer formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. By contrast, the Defendants argue that the term "PE" in the claims refers to general purpose PE, which excludes UHMWPE.

Plaintiff's expert, Dr. Matthew Hermes, provided the

scientific background, which is largely undisputed. PE is formed from repeating units of the monomer ethylene, (CH_2-CH_2). (Pl.'s Markman Br. Ex. 7 at ¶ 6.) PE may be referred to as $(CH_2-CH_2)_n$, where n equals a whole number and indicates the number of repeating monomeric units of ethylene in the polymer. The "molecular weight" of a PE chain is determined by the length of the chain (i.e., how high n is). UHMWPE is composed of the same monomer unit as any other polyethylene chain, but has a longer chain of the repeating ethylene monomer than "low molecular weight" or "medium molecular weight" PE. (Id. at ¶ 7.) In other words, the building block for a suture made from UHMWPE is a very long and heavy PE chain.

Claim One recites that the first yarn is composed of a fiber-forming material "from the group consisting of" seven specific polymers, including PE. The specification is clear that "PE" means polyethylene. '446 Patent col.4 l.27. This claim does not distinguish between kinds of PE possessing different molecular weights. The patentee did not limit the definition of PE. Cf. Pfizer, Inc. v. Teva Pharms. USA, Inc., 429 F.3d 1364, 1373 (Fed. Cir. 2005) (determining that the claim term "saccharide" should not be construed only to include polysaccharides having ten or less monomer units because the claim, like the specifications, did not contemplate such a limited definition).

Plaintiff has also introduced evidence that a person having ordinary skill in the art would understand PE to mean all polymers made from PE. Dr. Hermes opines: "One of skill in the art would have known that 'PE' means 'polyethylene' and means all polymers made from ethylene. PE is the generic name for all types of PE, including ultra high molecular weight PE." (Pl.'s Markman Br. Ex 7 at ¶ 9.) To support Dr. Hermes's opinion, DePuy Mitek points to several technical dictionaries stating that the term PE encompasses all polymers consisting of ethylene monomers, including UHMWPE. For instance, the Encyclopedia of Polymer Science and Engineering states that "polyethylene [is] the 'common (source-based)' name for all polymers made from ethylene." (Pl.'s Markman Br. Ex. 7, Tab B).

The Defendants, however, argue that UHMWPE is a rigid and inflexible synthetic compound that would never enhance the pliability or lubricity of a suture.[3] As one of Arthrex's experts, Dr. Debi Prasad Mukherjee, argues:

> In February 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to those of general purpose PE. Consequently, the two materials are generally used for very different applications and one is not a substitute for the other. It has been my experience that,

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[3]Plaintiff has introduced evidence that UHMWPE is lubricious. (See Plaintiff's Ex. 9 at 51:15-55:5). The parties do not clearly explain the difference, if any, between a lubricious material and a stiff material in the context of a suture. Both appear to be related to handleability and pliability.

> generally, when UHMWPE is intended to be included for a specified application, there is a special effort to make that fact known.

(Def.'s Markman Br. Ex. 12.) Although there is evidence that a person of ordinary skill in the art would understand that UHMWPE has different properties from other kinds of PE, Arthrex has introduced no evidence that one of ordinary skill would not understand the term PE to include UHMWPE.

Defendants argue that the prosecution history contains a disclaimer of the polymer UHMWPE, citing extensively to the discussion of the "Burgess reference" in the '446 Patent's history. (Def.'s Markman Br. Ex. 7-8.) The Burgess patent protects a type of braided fishing line that utilizes a high-tensile PE as part of its construction. In response to the rejection by the patent examiner of the suture claims based on the Burgess patent application, the applicant argued:

> One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement maybe the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact.

(DM1000196). (Emphasis in original). The applicant distinguishes Burgess: "In contrast, knot strength is not even mentioned in Burgess." (Id.) The applicant adds: "Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability....Although this thread has great strength

properties, it suffers from low elongation and, in turn, poor knot strength properties." (DM1000196). (Emphasis in original). The parties agree that "high-tensile polythene" is the European terminology for UHMWPE.

In overcoming the Burgess reference, the applicant does distinguish the suture from the fishing wire by drawing a distinction between materials used in the invention, pointing out the poor knot strength properties of high-tensile polythene. The Defendants argue that in distinguishing the heterogeneous braided suture from the fishing line composed of UHMWPE, the patentee limited the scope of its patent to ordinary general use PE. (Def.'s Markman Br. 12-13).

Plaintiff responds that the prosecution history is not a clear disclaimer of the UHMWPE. It emphasizes that the patent examiner and the applicant both routinely refer to the "high tensile polythene" described by the British Burgess patent as "polyethylene." (See, e.g., Pl.'s Markman Br. Ex. 3 at DMI000189.) By including "PE" in the list of polymers in the amended claim, Plaintiff contends, the inventors intended to include UHMWPE. Moreover, while the prosecution history does indicate that UHMWPE was not a preferred polymer because of its minimal stretchability, the applicant emphasized the distinction between the uses and purposes of the two devices:

> In view of the dissimilarities in property requirements between sutures and fishing line, there would be no

> incentive for a medical designer who wishes to improve the properties of a braided suture to study the art related to braided fishing lines. Even if he did use the teachings of fishing line art to modify a suture, then he would inevitably design an unacceptable suture.

(Pl.'s Markman Br. Ex. 3 at DMI000196-97.) In light of this language, Plaintiff's argument that there was never a clear disclaimer of UHMWPE is ultimately persuasive. See Andersen Corp. v. Fiber Composites, LLC, Nos. 05-1434, 06-1009, ____ F.3d ____, 2007 WL 188709, at *10 (Fed. Cir. Jan. 26, 2007) (citing Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1375 (Fed. Cir. 2005)) ("It is true that we have warned against importing limitations from the specification into the claims absent a clear disclaimer of claim scope.").

Pulling together all of these threads, this Court finds that an ordinary person skilled in the art of science and suture manufacturing looking to the plain language of the claim, the specification, and the prosecution history of the '446 Patent would conclude that "PE," as used in Claim 1, includes all polymers formed from a repeating ethylene monomer, including UHMWPE.

B. Meaning of "Consisting Essentially Of"

The second term disputed by the parties is the transitional phrase "consisting essentially of." Generally, three transitional terms are used in patent claims: (1) "comprising," which is an open term of transition (2) "consisting of," which is

a closed term of transition, and (3) "consisting essentially of," which is a partially open term perched between the extremes of the other two phrases. "In view of the ambiguous nature of the phrase," the Federal Circuit has opined that "consisting essentially of" "has long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (quoting PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998).

To determine those "basic and novel properties of the invention," the Court must look at the specification to determine "the goal of the invention as well as what distinguishes it from prior art." AK Steel, 344 F.3d at 1239-40 (holding that a limiting statement in the specification that silicon should not exceed 0.5% was a disclaimer which had an impact upon the meaning of the phrase "consisting essentially of aluminum.") The Court must also look at the prosecution history of a patent to determine whether an unlisted ingredient was excluded from the scope of a "consisting essentially of' claim. PPG, 156 F.3d at 1355.

Construing the "consisting essentially of" language in a patent claim can "at times blur the distinction between the separate steps in an infringement analysis." AK Steel, 344 F.3d

at 1240. Where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect, the issue may be resolved as a question of law. Id. In some situations, however, whether an additional ingredient materially affects the basic and novel characteristics of a patented invention is a question of fact for a jury. See PPG, 156 F.3d at 1357 (stating that it is the province of the jury to determine whether the iron sulfide had a material affect on the basic and novel characteristics of the patented glass).

The key question of claim construction for this term in Claim One involves discerning the basic and novel properties of the heterogeneous suture. Once this determination has been made, the Court can attempt to resolve the parties' disagreement over whether the surgical coating placed on FiberWire braided suture "materially affects" the basic and novel properties of the suture described by the '446 Patent. AK Steel, 344 F.3d at 1239.

The Defendants submit that this Court should construe the claim term "consisting essentially of" as follows:

> i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.
>
> ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

(Def.'s Markman Br. 16.) By contrast DePuy Mitek suggests:

> The 'novel and basic characteristics' of the invention are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid. *Consisting essentially of* excludes sutures that contain bioabsorbable materials as the first and second fiber-forming materials.

(emphasis in original) (Pl.'s Markman Br. 8.)

DePuy Mitek's primary argument is that the transitional phrase was inserted to exclude certain bioabsorbable materials in the prior art from the patent claims. The prosecution history demonstrates the "consisting essentially of" language was added by amendment. In the prosecution history, the examiner originally had rejected the claims based on two references - Doddi and Kaplan - which included braids of dissimilar materials. Plaintiff argues it amended the claims to exclude bioabsorbable materials from the first and second fiber-forming materials in order to further distance itself from this prior art.

In response to the examiner's rejection for anticipation by Kaplan, the applicant stated that in Kaplan, the "sheath yarn" was a "biocompatible yarn that is bioabsorbable or semi-bioabsorbable...In one embodiment the sheath yarn could also contain a non bio-absorbable yarn of one or more chemical compositions....Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn." (DMI 1000259). (Emphasis

added). Later, the applicant again distinguishes the prior art: "Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e., PTFE) and a second set of nonabsorbable yarn (i.e., PET). (DM 1000260).[4] Id. Thus the Plaintiff argues there is a clear and express disclaimer of bioabsorbable yarns in the prosecution history. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005).

Defendants contend that the prosecution history does not support this interpretation because the patent specification provides, "The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired." '446 Patent col.3 ll.63-65 (emphasis added). Still, under the doctrine of prosecution disclaimer, Plaintiff's argument that it clearly disclaimed bioabsorbable yarns to overcome the rejection seems persuasive. Nonetheless, this debate seems largely beside the point because the issue here involves coatings, not bioabsorbable yarns.

The Defendants contend that the invention's primary basic and novel characteristic is that it improves the handleability and pliability of a suture without significantly sacrificing any physical properties of the constituent materials of the device, like strength or knot tiedown. The specifications reveal that

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[4]In addition, the plaintiff pointed out that Kaplan taught that sheath yarns listed in the invention should not be used in sheaths.

the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10. The specification points out, "Unfortunately, the prior art abounds with attempts to improve specific properties of multi-filament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multi-filament sutures almost universally possess a surface coating to improve handling properties." Id. at col. 1 ll. 26-31. It continues: "All of the attempts described in the prior art have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability." Id. at col. 2 ll. 14-17. Of significance, the specification states:

> In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties."

Id. at col.2 ll, 32-37 (Emphasis added).

Plaintiff argues that increased pliability is a property only of the preferred embodiment, pointing to the passage that states: "For example, in preferred embodiments, the heterogenous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." Id. at col. 2 ll. 50-67. As shown above, this is a myopic view of the specification, which states throughout that a primary goal of the invention is to achieve enhanced pliability and handleability. The sterilized heterogeneous braids described in this patent seek to achieve a high degree of pliability and handleability by mechanically blending together two dissimilar synthetic yarns.

Therefore, this Court concludes that the basic and novel properties of the suture described in the '446 Patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability

without significantly sacrificing the physical properties of the constituent elements of the suture.

2. Summary Judgment

As noted previously, both DePuy Mitek and Arthrex have moved for summary judgment on the issue of patent infringement. However, the summary judgment record is a mess because of the multiple motions to strike, each with extensive appendices and confusing briefing. This Court has allowed Arthrex to supplement Dr. Gitis's expert report to correct certain typographical and computational errors. Moreover, DePuy Mitek has launched a Daubert challenge to Defendants' expert report, and it is difficult to figure out the various expert opinions on the affect of the coatings on the accused devices. Accordingly, this Court will deny these cross-motions for summary judgment without prejudice.

ORDER

Plaintiff's motion for summary judgment of infringement is **DENIED** without prejudice (Docket No. 36). Defendants' motion for summary judgment of noninfringement is **DENIED** without prejudice (Docket No. 39).

All parties are ordered to submit a single brief, not to exceed 20 pages, on the summary judgment issue of patent infringement within 60 days in light of the Court's construction of the '446 Patent. The parties shall file no additional motions

to strike, and there shall be no replies or sur-replies.

PATTI B. SARIS
United States District Judge

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Rebuttal Expert Report of Dr. David Brookstein

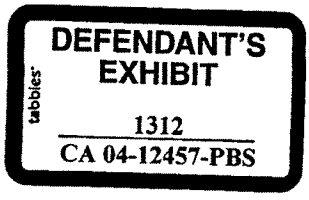
I. Background Information

1. I previously submitted an expert report in this case on March 3, 2006. I have been asked to opine on certain opinions expressed by Dr. Mukherjee in his report entitled the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters."

2. I have reviewed the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters," the documents referenced in my prior report and those listed in Ex. H attached hereto.

II. Summary of Opinions

3. I disagree with Dr. Mukherjee's opinion that there is no infringement under the doctrine of equivalents, if "PE," as used in the claims of the 446 Patent, is construed not to include UHMWPE.



4. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that FiberWire's coating does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

5. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that the nylon in TigerWire does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

6. If Dr. Mukherjee is correct regarding the meaning of "consisting essentially of" and the novel and basic characteristics of the invention, it is my opinion that FiberStick's adhesive does not materially affect the basic and novel characteristics of the suture claimed in the 446 Patent.

7. The reverse doctrine of equivalents does not prevent infringement.

8. I disagree with Dr. Mukherjee that FiberWire's benefits, which Arthrex promotes, are almost exclusively due to the UHMWPE in FiberWire.

III. If PE Is Construed Not to Include UHMWPE, FiberWire Still Infringes Under the Doctrine of Equivalents

9. As I explained in my previous report, if "PE" as claimed in the 446 Patent is construed not to include "UHMWPE," there is infringement under the doctrine of equivalents because the differences between UHMWPE and "PE" are insubstantial. Dr. Mukherjee has expressed opinions to the contrary. But I disagree with him for at least the following reasons.

10. As one basis for his opinion of substantial differences between "PE" and UHMWPE, Dr. Mukherjee opines that the 446 Patent describes the first fiber-forming materials as "lubricous but relatively weak" and alleges that the first fiber-forming materials are different than UHMWPE, which is known to have certain strength properties (Mukherjee Res. Report at 15). I disagree because the 446 Patent does not describe the first fiber forming materials as "lubricous but relatively weak." In fact, it never describes the first fiber-forming materials, including "PE," as

it is my opinion that the first fiber forming materials, such as PP, function to add tensile strength. Therefore, the differences are insubstantial.

21. Dr. Mukherjee disagrees with my opinion regarding equivalents because it is too broad. I believe that he misunderstands my opinion. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

IV. Under Dr. Mukherjee's Definition of "Consisting Essentially Of," FiberWire Infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent

22. As I understand the law, because the 446 Patent claims recite the phrase "consisting essentially of," if FiberWire has structure in addition to the structure listed in the 446 Patent claims, there is infringement, unless the additional structure materially affects the "basic and novel characteristics" of the claimed suture. Dr. Mukherjee opines that the "basic and novel characteristics" of the suture claimed in the 446 Patent are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18, Section VI.D.). According to Dr. Mukherjee, FiberWire's coating, TigerWire's nylon visual marker strand, and FiberStick's adhesive, each provide a "material" affect on this novel and basic characteristic that precludes infringement (Mukherjee Res. Report at 22, 30, 31). I disagree with Dr. Mukherjee's opinion and address each of his three points below.[2]

[2] Mr. Grafton's testimony and Arthrex's 234 patent support my opinion regarding the equivalence of UHWMPE and PE if "PE" is defined not to include UHMWPE as well as my opinion that there is no material affect on the novel and basic characteristics as set forth in my previous report for the reasons set forth herein. For example, they show that the differences are insubstantial because UHMWPE provides lubricity and PET provides knot holding strength.

A. If the Novel And Basic Characteristics Have The Definitions Provided By Dr. Mukherjee, FiberWire's Coating Does Not Materially Affect Them

23. According to Dr. Mukherjee, the novel and basic characteristics are "a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). Dr. Mukherjee opines that FiberWire's coating materially affects this novel and basic characteristic. I disagree for the following three reasons: (i) FiberWire was specifically engineered to have the properties described in the 446 Patent; (ii) the 446 Patent does not consider coating of the type used on FiberWire to have a "material" affect on the basic and novel characteristics; and (iii) Dr. Mukherjee's tests are flawed or inconclusive. I describe each of these three points below.

1. FiberWire Was Engineered to Have The Basic and Novel Characteristics, and the Coating Does Not Materially Affect Them

24. FiberWire's coating does not materially affect FiberWire's characteristics of having two dissimilar yarns (*i.e.*, UHMWPE and PET) braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. Both before and after the coating is applied to FiberWire, FiberWire has two dissimilar yarns (*i.e.*, UHMWPE and PET). Further, regardless of the coating, the UHMWPE and PET braid provides improved handleability and pliability performance without significantly sacrificing physical properties. The coating does not prevent or materially affect the two materials from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words because FiberWire still obtains the handleability/physical property benefits of the UHMWPE/PET braid after the coating is applied, the coating does not materially affect the novel and basic characteristics. FiberWire's coating is merely a surface "lubricant" (Mukherjee Res. Report at Ex. 16).

25. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, or from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by Arthrex's development and testing of FiberWire. Arthrex and Pearsalls had originally developed a suture having a homogeneous 100% UHMWPE braid. But they found it to have unacceptable knot holding strength properties (Ex. I at 52:24-53:7). The homogeneous UHMWPE braid was too lubricous to "hold a knot" (Ex. I at 45:16-46:15; 50:1-53:7). At the same time, Arthrex found that the same braided UHMWPE suture had other good "strength" properties (Ex. I at 46:7-8). I consulted with Dr. Hermes and, based on his opinion and because UHMWPE fibers are lubricous (Ex. I at 52:24-53:1), the UHMWPE braid would also have had some good handling properties including surface frictional properties, such as tactile feel. Also, the lubricous yarns would contribute to braid pliability because they allow the fibers to slide past each other when bent. Arthrex and Pearsalls also developed sutures having homogeneous polyester braids (Ex. S). According to Mr. Grafton, Arthrex found them to have lower knot pull strength than a braid of UHMWPE fibers and polyester fibers (Ex. S; Ex. I at 81:8-12). Thus, Arthrex thought that sutures having braids of UHMWPE and braids of polyester each had different drawbacks. Ultimately, Mr. Grafton braided UHMWPE with PET, which is a polyester, and found that the heterogeneous braid had improved knot holding strength properties; it did not slip like the UHMWPE braid he had made:

Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to

reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?
A. I've lost count, it's been so many times, but the answer again is yes.

(Ex. I at 53:2-54:5) (objections omitted). This type of UHMWPE and PET braid was ultimately marketed as FiberWire. Thus, Arthrex engineered a braid of UHMWPE and PET to maximize the benefits of the dissimilar yarns (Ex. I at 68:25-70:13). For example, UHMWPE in FiberWire's braid contributes to the braid's tensile strength, knot pull strength, pliablity, and lubricity/handling, and PET contributes to the braid's knot holding strength, and handling/pliability. Thus, Arthrex designed FiberWire to be braid of dissimilar yarns that has improved handleability and pliability performance without significantly sacrificing physical properties. Although FiberWire is coated, it is still a braid of dissimilar yarns having these benefits. Although the coating may enhance certain suture properties, the coating does not materially affect the fact that FiberWire has a braid with improved handleability and pliability performance without significantly sacrificing physical properties.

26. My opinion that FiberWire was specifically designed to have the novel and basic characteristics that Dr. Mukherjee attributes to the 446 Patent is further supported by other aspects of FiberWire's development. For example, during FiberWire's initial development, Mr.

Grafton asked Pearsalls to "build a 25% Dyneema/75% polyester *blend* in a size 2 that is *very flexible* (like the existing suture or the Ethicon sample)" (Ex. HH) (emphasis added). As Mr. Grafton stated, "[i]f we can get this blend correct, we will have a terrific advancement" (Ex. HH). According to Mr. Grafton, Arthrex varied the dissimilar braid materials in type and amount in order to optimize FiberWire's properties:

Q. I would like to know what you mean by in your letter when you said, "If we can get this blend correct." You asked them for a 25 percent Dyneema/75 percent polyester blend in Size 2 that's very flexible. And then you said, "If we can get this blend correct, we will have a terrific advancement." What did you mean by "If we can get this blend correct"?
A. The optimization of the two materials. If you had the knot strength, loop security, and tensile strength, as well as the tactile feel of the suture all superior to what was on the market, then it would be a superior product.
Q. Wait a second. You said optimization of two materials.
A. (Witness nods head affirmatively).
Q. At this point in time, November 1998, were you trying to vary the amount and type of the Dyneema and polyester in the braid in order to get the best properties?
A. During -- during the -- during that period of time, yes.
Q. So you were balancing off the properties of each material to try to get the optimum properties --
A. Tensile strength.
Q. To get the optimum tensile strength?
A. (Witness nods head affirmatively).
Q. What about knot security?
A. Yes.
Q. Okay. So you were varying the amount and type of the materials to get the optimum knot security, optimum tensile strength?
A. Yes.
Q. Any other properties? Knot tiedown?
A. The slideability of the knot, the tactile feel in the surgeon's hands of the material.
Q. So you were varying type and proportion of the

materials to optimize all these properties in the product?
A. Yes.

(Ex. I at 68:25-70:13). Further, as explained by Ms. Holloway, FiberWire was braided, so that the individual materials contribute to FiberWire's handleability:

Q. What materials contribute to the handleability of Arthrex's FiberWire sutures?
A. All materials used.

(Ex. T at 31:23-25). Thus, in designing FiberWire to have a dissimilar yarn braid, Arthrex specifically designed FiberWire to have the basic and novel characteristics that Dr. Mukherjee attributes to the 446 Patent: (i) a dissimilar yarn braid having the benefits of each yarn; and (ii) improved handleability and pliability without significantly sacrificing physical properties. Although FiberWire is coated, it still reaps the benefits of this dissimilar yarn braid in terms of handleability/pliability and physical properties. Therefore, the coating does not materially affect the novel and basic characteristics as defined by Dr. Mukherjee.

27. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is further supported by the fact that FiberWire has a very small amount of coating. In fact, it is so small that Pearsalls and Arthrex consider it unmeasureable (Ex. U at 119:5-9; Ex. V at 94:2-9; Ex. W at 48:1-50:16; Ex. X at ARM2104). I have personally observed and studied Pearsalls' coating processes for FiberWire during an inspection of Pearsalls' facilities in January 2006. FiberWire is coated by passing a braid of PET and UHMWPE, which has been dyed[3] and scoured, through a bath of NuSil Med 2174 polymer and Xylene solvent at a rate of 20 meters

[3] Most FiberWire is dyed blue. But some, such as TigerWire is not. Also, TigerWire has a braid that includes a Nylon marker band in place of one PET yarn.

per minute (Ex. U at 88:4-9; 82:14-18). Xylene is not a coating. Rather, Xylene is a solvent that dissolves the Med NuSil polymer, so that it can adhere to the FiberWire braid (Ex. U at 87:25-88:3; Video of Pearsalls' manufacturing). After passing through the solution, the coated FiberWire is passed through pads, which are compressed together, to wipe away excess coating (Ex. U at 97:1-18). Further, FiberWire is passed through a five-stage oven that dries the coating and evaporates the solvent (Ex. U at 95:14-17). The process is then repeated. I have measured the amount of coating by weight on FiberWire by determining the linear density (*i.e.*, grams/unit length) of a sample that was not coated, a sample that had been coated once, and sample that had been coated twice (DM Exhibits 284, 342, and 285). I determined that the linear density of Ex. 284 (uncoated) is 2393 denier, Ex. 342 (coated once) is 2474 denier, and Ex. 285 (coated twice) is 2508 denier using a traditional Mettler balance housed at the Philadelphia University Research Center Materials Evaluation Laboratory. Accordingly, the linear density of Ex. 342 indicates a 3.4% pick-up of coating material from the uncoated Ex. 284. The linear density of Ex. 285 indicates a 1.4% pick-up of additional coating material from Ex. 342. Thus, the total pick-up of Ex. 285 over Ex. 284 is approximately 4.8%. The result of this coating process is that, although FiberWire has a very small amount of coating, FiberWire still has two dissimilar yarns braided together to form a braid with improved handleability and pliability performance without significantly sacrificing physical properties. In other words, the coating did not transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided. For example, the coating is not applied in a very thick layer and then melted together with the yarns to form a non-braided structure. As Arthrex explains in its instructions for use, FiberWire's coating is just a "lubricant" (Mukherjee Res. Report at Ex. 16).

28. My opinion that FiberWire's coating does not materially affect FiberWire's PET and UHMWPE yarns from being dissimilar, from being braided, and from forming a braid with improved handleability and pliability performance without significantly sacrificing physical properties is supported by both my visual observations of FiberWire, as well as those by CETR. Both my photographs and CETR's show that, even at extreme magnifications, it is difficult to even see coating in certain areas of the suture. In fact, both sets of pictures show that FiberWire has fibers that retain their morphological attributes, so that they can contribute to the handleability, pliability, and physical properties of FiberWire.

29. Dr. Mukherjee opines that the SEM's attached to my expert report are "too unclear to draw any conclusions from them" (Mukherjee Res. Report at 30). But Dr. Mukherjee concludes based on these SEM's that the "coating has permeated into the braid" (Mukherjee Res. Report at 30). I do not understand how Dr. Mukherjee can say the SEM's are "too unclear to draw any conclusions" then make conclusions from the very same "unclear" micrographs.

30. I note that Dr. Mukherjee does not opine on the issue of whether FiberWire's coating materially affects the fact that it has a dissimilar yarn braid with improved handleability and pliability without significantly sacrificing physical properties. Rather, he seems to opine that FiberWire's coating affects certain individual properties. But that is not the relevant issue even as he defined the novel and basic characteristics. Rather, the relevant issue as he framed it was whether FiberWire's coating materially affected FiberWire from being a suture with "two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties" (Mukherjee Res. Report at 18). In my opinion, because FiberWire is specifically designed to have precisely these characteristics and its

coating is essentially a surface lubricant, FiberWire's coatings effects are not material to the novel and basic characteristics.

2. Based on the 446 Patent, FiberWire's Coating Does Not Materially Affect the Novel and Basic Characteristic

31. In order to determine whether an effect on the basic and novel characteristics, as those terms are defined by Dr. Mukherjee, is "material," I have consulted the 446 Patent to determine what it considers "material" or not "material." In other words, I have considered whether FiberWire's coating is "material" in the context of the invention described in the 446 Patent. Based on the 446 Patent's description of the invention and its description of coatings, FiberWire's coating does not "materially" affect the novel and basic characteristics, as defined by Dr. Mukherjee.

32. My opinion that FiberWire's coating does not have a "material" effect is based on the 446 Patent's explanation that "coating" is not "material" to the invention. As the 446 Patent explains, the direct intertwining braid of dissimilar materials provides "outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns" (Ex. D at 2:50-52). The 446 Patent further explains that such a braid can be further improved with a coating (Ex. D at 6:5-21). Thus, because the 446 Patent specifically contemplates applying coatings of the type used in FiberWire to refine certain braid properties, the 446 Patent does not consider coatings, of the type applied to FiberWire, to have a "material" effect on the basic and novel characteristics of the suture claimed in the 446 Patent.

33. I disagree with Dr. Mukherjee's opinion that FiberWire's coating has a "material" effect because he basically *excludes* coated sutures from the 446 Patent claims (Mukherjee Res. Report at 22). But this is just contrary to the teachings of the 446 Patent. As the 446 Patent describes, the inventors specifically contemplated preferred embodiments having coatings:

> If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to ***further*** improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. ***Most preferably***, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating ***may be*** eliminated saving expense as well as avoiding the associated braid stiffening.

(Ex. D at 6:5-18) (emphasis added). Thus, the inventors specifically *included* coatings within the description of the invention, not *excluded* them, as Dr. Mukherjee opines. Therefore, because the 446 Patent specifically contemplated coatings, such as that used in FiberWire, it is my opinion that FiberWire's coating cannot be deemed to have a "material" effect on the basic and novel characteristics of the invention.

34. My opinion that FiberWire's "coating" does not have a "material" effect is further supported by the fact that Arthrex and Pearsalls did precisely what the 446 Patent teaches to obtain the basic and novel characteristics that Dr. Mukherjee attributes to the suture claimed in the 446 Patent. The 446 Patent teaches forming a heterogeneous braid which has a first and a second set of continuous and discrete yarns (Ex. D at 2:40-41). FiberWire's UHMWPE and PET are braided in a heterogeneous braid and are continuous and discrete yarns. The 446 Patent teaches braiding a lubricous yarn with a yarn of different lubricity (Ex. D at 4:11-12; 4:33-40). Arthrex and Pearsalls do that; they braid UHMWPE, a lubricous yarn, with PET, a yarn of different lubricity. The 446 Patent teaches braiding dissimilar yarns in direct intertwining contact (Ex. D at 2:43-44). Arthrex and Pearsalls braided PET and UHMWPE yarns in direct intertwining contact (Ex. V at 107:5-8). The 446 Patent teaches that each yarn has a plurality of filaments (Ex. D at 2:45-48). FiberWire's braided UHMWPE and PET yarns each have a plurality of filaments, as shown in Exs. E-G attached to my first report and CETR's images. The 446 Patent teaches braiding yarns to obtain the benefits of each. Arthrex and Pearsalls do that as

is shown by its product development (Ex. I at 68:25-70:15). The 446 Patent teaches "to tailor" the physical braid properties "by varying the type and proportion of each of the dissimilar fiber forming materials used" (Ex. D at 2:59-61). Arthrex did just that by trying different types and amounts of UHMWPE and polyester (Ex. I at 68:25-70:15). The 446 Patent teaches coating the braid by immersing it in a solution of a coating polymer and a solvent (Ex. D at 6:9-10). Likewise, Pearsalls and Arthrex coat by passing FiberWire through a coating solution (see above). The 446 Patent specifically contemplates that coating can "***further***" improve the handleability of the suture (Ex. D at 6:5-18) (emphasis added). According to Dr. Mukherjee, FiberWire's coating further improves handleability (Mukherjee Res. Report at 22-23). The 446 Patent states a preference that coating does not adhere the yarns or fibers to one another thereby increasing stiffness (Ex. D at 6:11-13). As shown by the SEM's of the FiberWire, the fibers are not bonded together (Mukherjee Res. Report at Ex. 20 and Exs. E-G). Thus, because Arthrex and Pearsalls specifically engineered FiberWire to be a nonabsorbable heterogeneous braid, as is precisely described in the 446 Patent, the effects of FiberWire coating can hardly be considered material.

35. I further disagree with Dr. Mukherjee's focus on FiberWire's coating with reference to defining what is "material" because the 446 Patent is not about "coating" or eliminating "coatings." Rather, the problem addressed by the 446 Patent is how to improve multifilament braided suture properties. For example, the 446 Patent explains that some prior art attempted to improve braided multifilament suture properties at the expense of restricting the movement of adjacent filaments (Ex. D at 1:26-29). The 446 Patent then provides some prior art attempts including a certain polyester coating for multifilament sutures (Ex. D at 1:32-43), a PTFE coating (Ex. D at 1:43-54), a monofilament like surface on a multifilament braid (Ex. D at 1:55-

3:2), and an elongated core (Ex. D at 2:3-13). According to the 446 Patent, these techniques could be improved upon because they did not focus on improving multifilament properties by increasing fiber-to-fiber mobility (Ex. D at 2:14-17). Thus, the 446 Patent is not saying that coating was a problem that had to be solved. Rather, the 446 Patent is teaching that certain coatings and other techniques were insufficient *by themselves* to sufficiently improve certain multifilament suture properties.

36. As a solution to the issue of improving multifilament braided suture properties, the 446 Patent teaches braiding dissimilar fiber-forming materials in direct intertwining contact to form a heterogeneous braid, that has properties "attributable to the specific properties of the dissimilar fiber-forming materials" (Ex. D at 2:40-53). The 446 Patent also states that certain properties of the dissimilar yarn braid can be "improved" by a coating (Ex. D at 6:5-21). Thus, the solution to the issue of improving multifilament braid properties provided by the 446 Patent is to braid dissimilar fiber-forming yarns in direct intertwining contact. Thus, coatings were not material to the issue addressed by the 446 Patent, nor the solution provided. Therefore, the 446 Patent's description of the invention shows that it does not consider coating, as used on FiberWire, to have a "material" effect on the basic and novel characteristics of the claimed suture.

3. To The Extent That I Understand Dr. Mukherjee's Tests, They Are Irrelevant or Inconclusive

a) Dr. Mukherjee's Tests Are Irrelevant

37. I note that Dr. Mukherjee opines that "coating materially affects handleability," "knot security and knot strength" (Mukherjee Res. Report at 22 and 27). But he never opines on whether the coating materially affects the basic and novel characteristic that he attributes to the 446 Patent, namely two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing physical properties. According to Dr.

Mukherjee, FiberWire's coating affects certain individual suture properties. But the novel and basic characteristics that he attributes are not just individual suture properties. Rather, they are the benefits of braiding dissimilar yarns to improve one property (*e.g.*, handleability) without significantly sacrificing others (*e.g.*, physical properties). As explained above, FiberWire's braided construction has these benefits. Accordingly, any purported affect by FiberWire's coating cannot be considered material in the context of the invention.

38. Dr. Mukherjee seems to rely on the 446 Patent's statement about preferred embodiments for his rationale that a coating will materially affect the basic and novel characteristics of the invention. But he misstates the statement upon which he relies and therefore incorrectly defines material effects. The 446 Patent states that "in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional *homogeneous* fiber braids, without sacrificing physical strength or knot security" (Ex. D at 2:62-66) (emphasis added). Thus, the 446 Patent was discussing improved properties relative to *homogeneous* braids, not relative to *uncoated heterogeneous* braids of dissimilar yarns. Dr. Mukherjee ignores the reference to the homogeneous braid.

b) Dr. Mukherjee's Testing and Analysis Is Flawed

39. Dr. Mukherjee relies on Pearsalls' knot strength data (Mukherjee Res. Report Ex. 25), testing performed by Arthrex (Mukherjee Res. Report Ex. 19), testing performed by CETR (Mukherjee Res. Report Ex. 20), and "drape tests" performed by him and Dr. Burke (Mukherjee Res. Report at 27). I do not have sufficient information to fully analyze all of these tests. For example, I do not have information sufficient to determine whether the only difference between the tested samples was coating, how the samples were manufactured, the parameters of the test specifications, and whether the reported data was the complete data obtained from any and all tests performed. Nevertheless, I have formed opinions to the extent that I can, based on the

limited information with which I have been provided. Also, I note that CETR and Dr. Mukherjee appear to have analyzed and tested only FiberWire size #2 and appear to have applied that analysis without any explanation to all FiberWire products.

(1) Pearsalls' Knot Pull Strength Tests Show No Material Change in Knot Pull Strength

40. Dr. Mukherjee relies on Pearsalls' knot pull strength data summarized in Exhibit 25 to his Responsive Report for his opinion that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29). Exhibit 25 to Dr. Mukherjee's Responsive Report is a listing of the average knot pull strength per batch at the "dye" and "measure" stages. Dr. Mukherjee concludes from this data that the coating causes knot pull strength to materially increase. As I understand the data, the "dye" column is the average knot pull strength of a FiberWire batch that did not undergo the coating process that I observed at Pearsalls, and the "measure" column is the average knot pull strength of FiberWire that underwent the coating processes (Ex. U at 47;1-23 Exs. Y and Z). This data appears to show that, in a significant number of instances, the measured knot pull strength *decreased* from the dye to the measure stage and therefore decreased after coating was applied to the suture. Also, at times, the measured knot pull strength stayed exactly the same. Thus, I do not know how Dr. Mukherjee can conclude from data, a significant amount of which is contradictory, that coating causes an increase in knot pull strength. He provides no explanation for this contradiction. Also, it is not clear why he necessarily attributes the change in knot pull strength to be due to coating. He fails to consider the inherent differences in tying knots, which can affect results, manufacturing differences between the "dye" and "measure" samples, and the known large variability in testing textile properties. Mr. Hallet from Pearsalls even explained that variations in the data, which Dr. Mukherjee relies upon, can be due to testing differences, not the material, and the variations in

the data were not really variations (Ex. U at 244:4-6; 348:22-349:6). To the extent that Dr. Mukherjee is relying on the final "average" computed in Ex. 25, that is improper.

41. I further disagree that Dr. Mukherjee can conclude from Pearsalls' knot pull strength data that FiberWire's coating materially affects FiberWire's knot pull strength (Mukherjee Res. Report at 28-29) because he ignores entire sections of relevant data. Pearsalls' normal practice is to perform knot pull strength testing at three stages of manufacturing, namely, the "dye," "intermediate," and "measure" stages. But Dr. Mukherjee wholly ignored the "intermediate" test stage data. The "intermediate" test stage data shows some of the flaws in his analysis. I understand that the suture that is tested during the "intermediate" and "measure" stage has not had any change in materials or undergone different processing (Ex. U at 348:5-13). Therefore, the knot pull strength should not change for a given batch between the "intermediate" and the "measure" stages. But, as summarized in Exhibit AA, Pearsalls' testing shows that the measured knot pull strength was generally not the same at the intermediate and measure stages. Because Pearsalls measured "differences" in knot pull strength between the "intermediate" and "measure" stages, when one would have expected it to stay the same, it would not be correct to conclude that there was in fact a change in knot pull strength between the "intermediate" and "measure" stages. Likewise, absent some explanation, it is not correct to conclude that the knot pull strength is "changing" between the "dye" and "measure" stages. Rather, Pearsalls' tests show that the knot pull strength basically stays the same before and after coating and that variations are probably due to testing differences, such as how the knot was tied. In fact, Mr. Hallet was asked why, for some batches, the average knot pull strength stayed about the same between the "dye" and "measure" stages, but went up at the "intermediate" stage (Ex. U at 341:16-344:25; Ex. BB). Mr. Hallet stated that the differences were probably due to the "operator" or the way the knot

was tied (Ex. U at 343:3-12). Also, Mr. Hallet testified that some changes were not really changes and were considered "about the same" (Ex. U at 344:22-25; Ex. CC). Further, when asked why, for one batch, the average knot pull strength went from 14.83 at the "intermediate" stage to "16.87" at the measure stage, Mr. Hallet attributed it to the "operator" (Ex. U at 346:21-347:1). Further, after reviewing the variations in some batches between the dye, intermediate, and measure stages, Mr. Hallet concluded that the data does not really show any variations in average knot pull strength:

> Q Well, if you look at the testing you cannot really say -- are they all within the tolerance of the testing so that you cannot really say that one of these values is greater than the other?
> A Yes.
> MR. BONELLA: That's correct
> A Yes.

(Ex. U at 348:22-349:6) (objection omitted). Thus, based on my review of Pearsalls' data and Mr. Hallet's explanation of the source of the data, I disagree with Dr. Mukherjee's opinion that he can conclude from the data in Exhibit 25 to his report that FiberWire's coating increased FiberWire's knot pull strength. If anything, Pearsalls' data show that FiberWire's coating has no material effect on knot pull strength.

(2) Arthrex's "Knot Tiedown" Test Is Inconclusive

42. With respect to Arthrex's "knot tiedown" test (Mukherjee Res. Report at Ex. 19), I am unable to draw any definitive conclusions from these tests because Dr. Mukherjee has not provided information about specifically which samples were tested. Also, with respect to Arthrex's "knot tiedown" test, I believe the test is not proper for the reasons expressed by Dr. Hermes.

(3) CETR's Tests Are Flawed and Inconclusive

43. Dr. Mukherjee relies on the CETR tests. But the CETR report does not explain what was tested other than "two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated." Without further information about the construction, manufacturing, processing, and handling of the samples, I cannot completely comment on the CETR tests. Further, the testing methodology is not completely clear from the CETR report. Thus, I cannot fully comment on the tests that CETR conducted.

44. Even assuming that the only difference between the two tested samples is coating, the tests are also inconclusive for the following reasons. Dr. Mukherjee uses the CETR "pliability test" to determine the effect of coating on pliability. But the "pliability test" described in section 5 of the CETR report, and the data derived from this test, are flawed for at least three reasons: (i) the purported "pliability" test uses a *tensile* test to imply pliability; (ii) the "pliability" test incorrectly assumes that *multifilament* FiberWire acts as a *monofilament*; and (iii) the "pliability" assumes a circular cross-section and a constant diameter of the suture. I address each of these errors below.

45. The test described in section 5 of the CETR report is a *tensile* test in which the FiberWire samples were not bent; it is not a *bending* test. It is basic mechanical and textile engineering that tensile tests generally cannot be used to determine bending properties in and of themselves. Typically, a tensile test places a sample in tension by extending it to a given strain level and measuring the dependent variable, tension. In contrast, a typical bending test applies a bending moment to a specimen, measures the amount of deflection in response to the bending moment, and determines from this data a bending modulus or bending rigidity. A tensile test can be used to determine the bending modulus only in the unique circumstance when the material that makes up the specimen's tensile and compressive moduli are equal and the material is monolithic, such

as certain monofilaments. By using a tensile test to determine bending rigidity, CETR assumes that coated FiberWire's tensile and compressive moduli are equal and uncoated FiberWire's tensile and compressive moduli are equal. Neither CETR nor Dr. Mukherjee provided any basis for this assumption. Without testing to prove that this assumption is correct or an explanation as to why it can be assumed, the "pliability" tests conducted by CETR are flawed.

46. The second reason the CETR "pliability" test is flawed is because it incorrectly assumes that *multifilament* FiberWire is a *monofilament*. CETR used the test method advanced in the Rodeheaver paper (Mukherjee Res. Report at Ex. 13) to determine FiberWire's pliability. But the mathematical relationship used by Rodeheaver to determine pliability assumes that the tested suture is a *monofilament* (Mukherjee Res. Report at Ex. 13 at 528). By assuming a monofilament structure, CETR simplistically assumes that a multifilament suture's pliability can be determined by measuring the tensile modulus, measuring suture diameter, and determining the moment of inertia of the suture. But FiberWire is a *multifilament* suture. To determine the bending rigidity of a multifilament textile structure, such as a suture, using the Rodeheaver equation is erroneous. It is well known in the textile field that a multifilament structure's bending rigidity is proportional to the number of filaments, the modulus of elasticity, the fiber-to-fiber mobility and *the individual moment of inertia of each filament.*[4] In other words, the fiber-to-fiber mobility of the multifilament structure will affect the effective structural moment of inertia. Therefore, the Rodeheaver equation cannot be used to determine the pliability for FiberWire.

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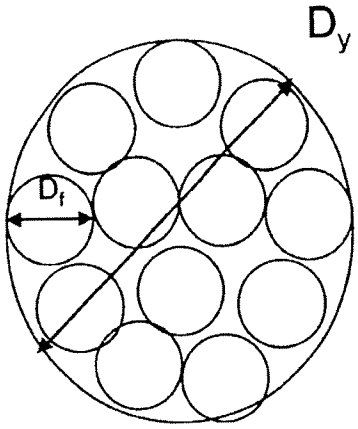
[4] *Mechanics of Elastic Performance of Textile Materials, Part XIV: Some Aspects of Bending Rigidity of Singles Yarns*, Platt, M., Klein, W. and Hamburger, W., Textile Research Journal, August 1959 pp. 611-627 (Ex. DD).

47. To understand the errors in Dr. Mukherjee's analysis, consider three example structures and how their bending strength or pliability can be determined. First, consider a monofilament of constant material (and assuming an equal compressive and tensile moduli) and cross-sectional circular shape ("monofilament"). The Rodeheaver test is applicable to such a monofilament structure. Second, consider a multifilament which has total freedom of inter-fiber movement during bending ("multifilament"). Such a multifilament's bending properties can be understood with reference to the 1959 seminal paper by Platt, Klein and Hamburger (Ex. DD). As Platt et al. describe, for a multifilament having complete freedom of fiber movement the product of the bending modulus (E) and the moment of inertia (I) of a yarn is proportional to $N_f E_f I_f$ where N_f refers to the number of individual fibers, E_f refers to the individual fiber modulus, and I_f refers to the moment of inertia of an individual fiber. Third, consider a multifilament that does not have total freedom of inter-fiber movement during bending. The monofilament and multifilament (having complete fiber mobility) can be considered two extreme conditions with the multifilament not having complete freedom of fiber movement being between the other two conditions. Because FiberWire's structure is a braided multifilament, there cannot be complete freedom of fiber movement.

48. To understand the error in Dr. Mukherjee's analysis, I will contrast a hypothetical monofilament structure with a hypothetical multifilament with complete freedom of inter-fiber movement with reference to the Figure below (each multifilament acts independent of its neighboring filament).



Assume $4*D_f = D_y$. For a monofilament type structure, the moment of inertia would be $\pi D_y^4/64$, which is the equation used by CETR and originally advanced by Rodeheaver. But for a multifilament having 12 fibers and total freedom of movement, as shown in the picture, the moment of inertia is $12*\pi D_f^4/64$. Accordingly, the monofilament's and multifilament's moment of inertia, and therefore their bending rigidity, are not equal. Because FiberWire is neither a monofilament nor a multifilament having complete independent fiber movement, its bending stiffness is somewhere between a monofilament and multifilament structure. Thus, assuming FiberWire is a monofilament, as Dr. Mukherjee and the CETR testing assume, also produces errors.

49. The third reason that I disagree that Dr. Mukherjee can draw conclusions from CETR's "pliability tests" is that CETR incorrectly assumes that the FiberWire samples have a circular cross section and that the diameter of each FiberWire suture is constant and equal to 0.65 mm. (Mukherjee Res. Report at Ex. 20 at 3). The Rodeheaver paper assumes a constant circular cross section. Dr. Mukherjee and CETR do not provide any basis for the assumption that the FiberWire samples have a constant circular cross section. The Rodeheaver paper also assumes a

constant diameter along the linear axis of the tested structure. Dr. Mukherjee and CETR do not provide any basis for the assumption that the tested FiberWire samples have a constant diameter along their linear axis. I have consulted with Dr. Matt Hermes. Based on his experience, he opined that even amongst the same USP size suture, suture diameters vary along their linear axis. I have reviewed the attached summary of Pearsalls' batch records, and they show variation in FiberWire's diameter for sutures made from same batch (Ex. AA). For example, the suture diameter varies between the "dye" (uncoated) and "intermediate" (coated) stages, as well as between the "intermediate" and "measure" stages. Thus, FiberWire varies in diameter, and it was incorrect for Dr. Mukherjee and CETR to assume that it does not. This error in assuming that the diameter is always the same is magnified to the fourth power because, in the monofilament equation used by Dr. Mukherjee, the diameter of the suture is raised to the fourth power (Ex. 20 of Mukherjee Res. Report at 3).

50. I also note that CETR's "pliability test" graph is not an accurate depiction of the tensile stress-strain relationship. CETR uses a non-linear, non-logarithmic scale on the horizontal axis. This distorts the true slope of the data. Also, I am not sure whether CETR reported all of its data in this graph or a portion of the data. I note that the data reported seems to be only part of a stress-strain curve that is obtained from a typical tension test. I know this because Figure 2 does not show the strain to failure of either of the samples.

51. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by his "knot slippage strength tests" and "knot run-down tests." I have consulted with Dr. Hermes and, from what we know about these tests, they are basically a type of tension test, similar to the "pliability" test conducted by CETR. Therefore, the slope of the curve from these tests before slippage or run down should be similar to that

obtained in CETR's "pliability" test. But they are not. During the pliability tests, CETR found that the coated suture had a lower modulus, as shown by its smaller slope (Mukherjee Res. Report at Ex. 20 at 3-4). In contrast, the other two CETR tests report a higher modulus for the coated suture, but it is not clear by how much from the graph and data (Mukherjee Res. Report at Ex. 20 at 5-8). The point being that the tests results are inconsistent. They appear to contradict the conclusions drawn by Dr. Mukherjee from the CETR "pliability" tests. Based on the limited information that I have about the tests, they are either inconclusive or show that coating has no material affect on tensile strength because the variations are due to the testing, not the material.

52. I also disagree with the conclusions that Dr. Mukherjee draws from the "pliability" tests because they appear to be contradicted by Pearsalls' testing. Ex. AA summarizes the results of Pearsalls' tension tests on batches of FiberWire at the "dye," "intermediate," and "measure" stages. Pearsalls found that FiberWire's tensile strength basically stayed the same between the uncoated FiberWire and FiberWire that underwent the coating processes. Although there are some variations in the reported measurements (*i.e.*, the tensile strength appears to go up, down, and stay the same), it is my opinion that these are really just an artifact of the testing (*i.e.*, operator variations, knot tying, or the expected variations inherent to textile testing) and not true variations (see paragraphs 40-41). I note that Dr. Mukherjee ignores these data in his analysis.

(4) Dr. Mukherjee's "Drape" Test Is Flawed & Inconclusive

53. I have considered Dr. Mukherjee's "drape test." This "test" is overly simplistic and flawed. Dr. Mukherjee states that he performed his drape test by "draping the suture over [his] extended index finger and observing the degree to which the suture conforms to the shape of [his] finger" (Mukherjee Res. Report at 27). First, I do not understand what he means by "conforms to the shape of my finger." Therefore, I cannot fully respond to his statement

because, among other reasons, I cannot tell what he measured. Second, it appears that Dr. Mukherjee is attempting to approximate FiberWire's pliability by determining FiberWire's ability to bend by using his finger as a test rig. But this method is flawed because he did not provide a true cantilever end support. Consequently, there is no defined position as to where FiberWire begins its bending, and no definitive way to determine the degree of bending. Third, diameter affects pliability, and Dr. Mukhejee does not provide any diameter measurements for the samples that he compared. Therefore, based on what I can determine from his report, it is not possible to scientifically compare the pliability of the uncoated and coated FiberWire using this method.

54. I note that Dr. Mukherjee relies on documents that refer to Ethicon and Mitek products in his analysis (Mukherjee Res. Report at 23-24, Mukherjee Res. Report Exs. 14, 15, 17, & 18). I disagree that these documents are relevant to the analysis because they discuss products and coatings that are different than FiberWire. It is my opinion, that the effect of FiberWire's coating on FiberWire cannot be determined with reference to other products.

B. If Dr. Mukherjee Is Correct Regarding The Meaning Of The Novel And Basic Characteristics, TigerWire's Nylon Does Not Materially Affect Them

55. Dr. Mukherjee has opined that TigerWire does not infringe for the same reasons that he expressed regarding FiberWire (Mukherjee Res. Report at 30). I disagree for the reasons stated above with respect to FiberWire.

56. I understand that the differences between TigerWire and FiberWire are that TigerWire is not dyed blue and replaces one PET yarn strand with one black nylon yarn strand. Dr. Mukherjee opines that TigerWire's nylon materially affects pliability (Mukherjee Res. Report at 30-31). I disagree. The purpose of the nylon strand is for visual identification (Ex. V at 74:21-23). It is my opinion that replacing one PET yarn with one nylon yarn does not materially affect

68. I reserve the right to comment further on Dr. Mukherjee's analyses and report when more information about the analyses becomes available. I may use trial demonstratives to explain my opinions.

Dated: April 13, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants.	)	Civil No. 04-12457 PBS

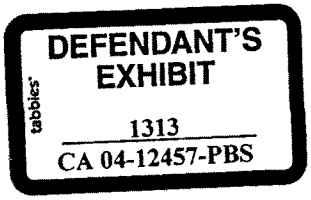
Amended Supplemental Expert Report of Dr. David Brookstein

I. Background Information

1. Based on new information presented to me since my last report, I submit this supplemental report. Additional information that I have reviewed in forming my opinions is attached as Exhibit II.

II. Summary of Opinions

2. The samples tested by Dr. Gitis that he labeled "coated" and "uncoated" were manufactured differently. These manufacturing differences affect FiberWire's UHMWPE/PET braid. Therefore, it is my opinion that neither Dr. Gitis nor Dr. Mukherjee can make any scientifically reliable conclusions about the effect, if any, of FiberWire's coating based on Dr. Gitis' tests because they could not and did not determine what effects may be due to the coating and what effects may be due to the manufacturing differences between the samples (*e.g.*, the differences by which the UHMWPE/PET braids were made).



surgery (Ex. AAA, Burks Dep. at 51:12-14). Thus, Dr. Burks' testimony regarding the use of gloves supports my opinion that the differences between the treated and untreated sutures are not material.

Dated: July 24, 2006

David Brookstein, Sc.D.
Fellow-American Society of Mechanical Engineers

Exhibit 4

Slip Copy, 2006 WL 2246416 (D.Mass.)
(Cite as: Slip Copy)

C

Watson v. Electrolux Professional Outdoor Products, Inc.
D.Mass.,2006.
Only the Westlaw citation is currently available.
United States District Court,D. Massachusetts.
Michael WATSON, Individually, and as father and next friend of John Watson, PPA, Plaintiff,
v.
ELECTROLUX PROFESSIONAL OUTDOOR PRODUCTS, INC., Defendant.
Civil Action No. 04-11782-DPW.

Aug. 4, 2006.

James E. Byrne, Thomas Drechsler, Jonathan E. Tobin, Finneran, Byrne & Drechsler Eastern Harbor Office PK, Neponset Circle, Dorchester, MA, for Plaintiff.
David A. Barry, Suleyken D. Walker, Sugarman Rogers Barshak & Cohen, P.C., Boston, MA, for Defendant.

MEMORANDUM AND ORDER
DOUGLAS P. WOODLOCK, District Judge.
***1** Plaintiff Michael Watson ("Watson") alleges in this product liability action that he was injured while using a defective work tool-a power cutter designed and manufactured by Partner Industrial Products ("Partner"), a division of the defendant, Electrolux Professional Outdoor Products, Inc. (" Electrolux").

Electrolux seeks to preclude testimony by Watson's expert witness on grounds that: (1) plaintiff has failed to demonstrate that his expert, Leslie N. Wilder, P.E. ("Wilder") is qualified to render admissible opinions as to the design of the power cutter; and (2) Wilder's opinion that the power cutter is unreasonably dangerous is unreliable because it is not supported by sound reasoning or sufficient facts. In short, defendant contends that Wilder's opinions are "sheer *ipse dixit* " and should therefore be precluded. *See generally Cipollone v. Yale Indus. Products, Inc.*, 202 F.3d 376, 380 (1st Cir.2000).

Contingent upon the outcome of the motion to preclude, Electrolux has also moved for summary judgment, claiming that expert testimony is essential to Watson's case, without which Watson will be unable to prove the saw was defective.

Finding that Watson's expert witness is qualified and that he proffers an admissible explanation for the cause of the injury, I will deny the defendant's Motion to Preclude his testimony regarding the " Blade Brake" theory. As to the merits, I find that a genuine issue of material fact exists regarding whether the lack of a blade brake (1) constitutes a design defect; and (2) caused plaintiff's injury. Accordingly, I will also deny Electrolux's Motion for Summary Judgment as to the Blade Brake theory. However, I will preclude expert testimony as to the "Trigger Lock" theory and grant summary judgment as to that claim (and the inadequately argued "warning" theory) because I find the expert's methodology as to an alternative theory inadequate and that without such expert testimony Watson will be unable to prevail on an alternative theory.

I. BACKGROUND

A. Facts

On May 5, 2001, Michael Watson was working as a highway construction laborer on the Central Artery Project or "Big Dig". The environment was noisy and lighted by portable lighting units. Watson was using an electric power saw which he identifies as a model K2300,[FN1] manufactured by Partner, a division of the defendant, Electrolux, to cut rebar located approximately 10 feet above the floor of the tunnel. Plaintiff had frequently used the saw [FN2] to cut rebar in the tunnel, and in the week prior to his

accident, that was plaintiff's exclusive job.

> FN1. The K2300 consists of an electric motor mounted in a housing. The motor drives a set of gears that, in turn, cause a blade mounted on front of the saw to spin rapidly. There is a front handle and a rear handle on the saw. It is equipped with a blade guard and an interlock mechanism. The interlock mechanism requires that the button, or "trigger lock," which is mounted just below the trigger and on the inside of the rear handle of the saw, be pushed before the trigger can be pulled.
>
> FN2. Defendant does not recall whether he was using a 12 or 14 blade version saw.

Watson would cut rebar protruding from the wall. The rebar were spaced about three feet apart, and ran from the floor of the tunnel to the ceiling-a distance of between fifteen and twenty feet. After cutting rebar in a particular section, Watson would climb down a ten to twelve foot high aluminum ladder holding the saw before moving the ladder to a different location.

***2** At the time of his accident, Watson had climbed up to the fifth or sixth rung of a ladder. From there, he grasped the saw by holding the rear handle with his right hand and the front handle with his left hand. He activated the saw and cut the rebar. After finishing the cut, he took his right hand off of the rear handle and deactivated the saw as he released the trigger. Watson then readjusted his left hand on the front handle of the saw and reached over with his right hand to make sure the cut rebar was flush with the wall. After determining that the rebar had been cut flush with the wall, Watson again repositioned his left hand on the front handle of the saw so that he could support the saw while holding onto the ladder with his right hand and descended to the ground. When he got to the bottom of the ladder, Watson took his right hand and gripped the saw by the front handle then removed his left hand from the front handle and gripped the saw by the rear handle with his left hand.

After lowering the saw to his side, and while gripping the rear handle of the saw with only his left hand, Watson felt the blade come into contact with his leg. At first he didn't know what happened, but when he went to take a step he could not feel his foot and realized that he had been injured. Watson suffered deep lacerations to the peroneal nerves in his left leg as a result of the accident. He has permanently lost feeling and control of his left foot, resulting in a foot drop, which causes him to have difficulty with his balance and to walk with an altered gait.

Prior to the day of the accident, Watson had no difficulty with any of the mechanisms or operation of the subject saw and, on the day of the accident, the interlock was operational. Watson does not know whether the blade was still spinning as he was going down the ladder, nor does he know whether he reactivated the saw between the time he released his finger from the trigger after making his last cut and when his accident occurred. At no time did Watson deactivate the interlock on the saw. Watson does not know what happened to the saw involved in his accident and never saw it after the accident.

II. DISCUSSION

A. Expert Testimony

Liability in this case hinges on the explanation of how the subject saw injured Watson, and whether this injury was due to a defect in product design. Plaintiff offers expert testimony to meet his burden of causation and design defect.

1. *Qualifications*

i. Standard of Review

Expert testimony may be presented as to "the precise nature of the alleged design defect and the causal relationship between the defect and the plaintiff's accident" where the knowledge on which evaluation rests is technical and specialized, and

consequently would not be within the ordinary experience of a jury. *Goffredo v.. Mercedes-Benz Truck Co.,* 402 Mass 97, 104 (1988).

A person may be qualified as an expert based on knowledge, skill, experience, training or education. Fed.R.Evid. 702. *See generally Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 153 (1999) (finding a witness with a masters degree in mechanical engineering, 10 years' work at Michelin America, Inc., and testimony as a tire failure consultant in other tort cases qualified to testify in a tire failure case); *Daubert v. Merrell Dow Pharmaceuticals, Inc,* 509 U.S. 579 (1993).

***3** The trial judge has broad discretionary powers in determining whether the proposed expert is qualified. Fed.R.Evid. 702; *see generally United States v. Sepulveda,* 15 F.3d 1161, 1183 (1st Cir.1993) (citing *Daubert,* 509 U.S. at 591). An expert's qualifications must relate to the subject matter of the proposed testimony. *Polaino v. Bayer Corp.,* 122 F.Supp.2d 63, 68-69 (D.Mass.2000). Experience that has been gained solely through litigation is generally accorded little weight. *See Thomas J. Kline, Inc. v. Lorillard, Inc.,* 878 F.2d 791, 800 (4th Cir.1989).

ii. Analysis

Electrolux opposes consideration of the opinions offered by Watson's expert witness, Leslie N. Wilder, P.E., contending that he is unqualified to render an opinion as to the design of the power cutter in question. In support of its argument, Electrolux argues that Wilder has no background, experience or training with power cutters-Wilder has never designed a motor brake, or tested a power cutter with a brake, nor has he designed any type of power saw or power cutter, blade brake, or trigger lock, or worked in the power saw industry.

Wilder is a licensed professional engineer in three states, with Masters Degrees in Mechanical Engineering from Stanford University and in Electrical Engineering from New York University. He is a board certified forensic engineer and professional ergonomist. He has worked as an engineer for forty-two years.

In addition, Wilder has practical experience in the private sector regarding aspects of mechanical, electromechanical, and electronic product development, manufacturing and marketing. He has worked as lead engineer with the responsibility for product development and manufacturing, including four years with the Hopp Press Inc., two years with Mechtronic Corporation, and five years as Director of Engineering at AMF Incorporated. Wilder has been responsible for a range of product lines including lawn and garden tractors, exercise equipment, motorcycles, telephonic equipment, electronic measuring devices and electronic switches and relays. He also holds fourteen patents which involve the design of electronic devices. He has testified as an expert witness and has investigated 22 accidents involving a variety of power saws.

Although defendant argues that Wilder's experience dealing with saws has derived from his work in litigation, this is not in and of itself a reason to preclude his testimony. Wilder's past history of testifying as expert engineer in jurisdictions including United States District Courts in New York, New Jersey and Connecticut-including cases involving power saws-may not add great weight to his qualifications, but it is certainly no basis for precluding his testimony. While the 2000 Advisory Committee Notes for Fed.R.Evid. 702 list whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" as a factor courts have found relevant in determining whether the testimony is sufficiently reliable, I find such considerations more appropriately addressed here as a question of credibility for the factfinder, because the factor on balance supports the admissibility of his testimony in this case.

***4** I find that Wilder's education, training and practical experience working as a professional engineer, and in designing, manufacturing and marketing electromechanical devices are sufficient to permit his expert testimony for such assistance as

the jury chooses to credit in understanding the technical and scientific evidence regarding the saw-an electromechanical device-in this case. Fed.R.Evid. 702.

2. *Testimony*

. *Standard of Review*

Under Fed.R.Evid. 702, a witness may testify as an expert if: "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." The rule thus imposes a gate-keeping role on the trial court to ensure that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand. *See generally Daubert,* 509 U.S. at 600; *Kumho,* 526 U.S. at 149, 156.

Daubert lists five factors that may be taken into consideration in determining whether expert testimony is admissible: (1) whether the expert's technique or theory can be or has been tested-that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publications; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community. 509 U.S. at 592-94. These factors may also be applicable in assessing the reliability of non-scientific expert testimony. *Kumho,* 526 U.S. at 147-49 (applying *Daubert* to the "expert" testimony of an engineer in tire failure analysis"). *Kumho* also holds that the list is not meant to be a definitive checklist or test. Whether any or all of these factors are considered is tied to the facts of a particular case. *Id.* at 150. Thus, the inquiry is a flexible one, and gives the trial judge broad latitude to determine whether the expert employs the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152. The ultimate purpose of the *Daubert* inquiry is to determine whether the expert's testimony would be helpful to the jury in resolving a fact in issue. *Id.* at 147; *Cipollone,* 202 F.3d at 380.

Where the facts in issue necessitate expert testimony but do not clearly point to a determinative cause of the accident, an expert may infer a " plausibl[e]" explanation from the evidence. *Pace v.. Ins. Co. of N. Am.,* 838 F.2d 572, 578 (1st Cir.1988) . However, "the inferences must be reasonable and must be based on probabilities rather than possibilities and may not be the result of mere speculation and conjecture." *Goffredo,* 402 Mass. at 101. Speculative testimony will not satisfy a plaintiff's burden of establishing by a preponderance of the evidence that a design defect was the proximate cause of his injuries. *Fidalgo v. Columbus McKinnon Corp.,* 56 Mass.App.Ct. 176, 183 (2002).

***5** Once the trial court determines the reliability of the expert's methodology and the validity of his reasoning, the expert should be permitted to testify as to inferences and conclusions he draws. Any flaws in his opinion may be exposed through cross-examination or competing expert testimony. *U.S. v. Mooney,* 315 F.3d 54, 63 (1st Cir.2002).

i. Analysis

Here, Wilder opines that the presence of the deep laceration in Watson's left leg indicates that the blade was rotating at the time it came in contact with his leg. Wilder has proffered two reasons for why the blade was rotating when it contacted Watson's leg: (a) the saw did not have a blade brake to reduce the coasting of the blade quickly after deactivation (the "Blade Brake theory"); and/or (b) the location of the interlock on the saw permitted Watson to activate the saw inadvertently (the " Trigger Lock theory"). A third "warning" theory is suggested in the papers of the case, but not argued.

a. "Blade Brake" Theory

Defendant opposes Wilder's Blade Brake theory because Wilder never designed or tested his proposed blade brake in a power cutter, the product at issue in this case. For this reason, defendant argues that Wilder's opinion is not supported by a reliable engineering methodology or sufficient facts or data, as required by Federal Rule of Evidence 702 .

However, Wilder did conduct a number of tests with an exemplar K2300 including: simulation of the accident sequence, timing of the coasting blade, fast action photography to determine spin up time of the blade, cuts with the saw, manipulations to determine if the saw could be activated inadvertently, and general handling of the saw to understand its operational characteristics. Wilder repeatedly simulated Watson's accident to determine how long it would take to descend the ladder, and change the saw from one hand to the other. This averaged out at nine seconds. He performed coast down tests on an exemplar 12 saw, in which he again and again timed how long it took the blade to stop after release of the trigger. This averaged 12.7 seconds.

Wilder examined other electric saws, similar to the K2300, equipped with blade braking mechanisms. He found that blade-braking mechanisms on electric saws with rotating blades are commonly used, that the technology to employ such a mechanism has been readily available since the 1960's, and that it could have been installed at a minimal cost to the manufacturer.[FN3]

> FN3. For the Makita 5007NB, the addition of an electric brake feature-the cost difference between the two saws was $10. For the DeWalt circular saw, model DW369CSK and DW368 model, which differ only in that the former includes an electric brake, the cost difference between the two was between $5 and $7.

Based on his testing, Wilder concluded that approximately nine seconds would have elapsed from when Watson powered down his saw to the point of injury and that an abrasive blade on the saw measuring twelve or fourteen inches could have been made to stop in approximately two seconds with such a brake. Without a blade brake the blade will continue to spin for 10-15 seconds after deactivation.

I find that Wilder's testing of the saw's coast down times is based on generally accepted engineering principles, and can give rise to admissible testimony on the issue of causation. His opinion satisfies Fed.R.Evid. 702 in that it is based upon sufficient facts or data (repeated testing), is the product of reliable principles and methods (repeated timing with a stop watch), and employs methods that have been applied reliably to the facts of the case (accident simulations).

***6** Wilder also determined that a blade brake would have prevented Watson's injury because it would have stopped the subject saw within two seconds, and the time between Watson's turning off the saw and the injury was approximately nine seconds.[FN4] Although Wilder's blade brake calculations are more speculative because he did not use the K2300 in these tests, I find that his methods are acceptable under Fed.R.Evid. 702.

> FN4. Wilder tested the DeWalt DW 369CSK by mounting two 10-inch steel blades on the saw. These blades had greater combined polar moment of inertia than the K2300 14-inch abrasive blade. The DeWalt stopped in two seconds. Wilder also tested Delta and Ridgid miter saws of similar power, functionality, size and price as the subject saw. Wilder found stopping times of 2.6 seconds and 2 seconds respectively. However, the Ridgid model had a free coast down of only 5.5 seconds, while the coast down of the K2300 was 10-15 seconds.

Wilder could not have used a K2300 to perform these tests because no K2300s are manufactured with blade brakes. Defendant suggests that Wilder should have somehow installed a blade brake on the K2300. That step, while no doubt instructive, is not necessary. Wilder's repeated testing of similar saws,

one of which was heavier than the K2300, is sufficient to establish that coast down times would have been shorter had the K2300 been equipped with a brake.

b. Trigger Lock Theory

Defendant opposes Wilder's Trigger Lock theory contending it was not presented in a timely fashion (Wilder communicated his theory to defendant in a letter dated March 24, 2006, just three days before his deposition, and long after the September 30, 2005 deadline set by this court); it is unreliable because it is based on a factually mistaken interpretation of a videotape produced by the defendants; experimentation with an exemplar cutter was limited; the underlying hypothesis as to what might become "instinctive" or "second nature" is speculative; and the proposed alternative design represents a mere "concept" that he never designed or tested; there is insufficient basis to show that the location of the trigger lock caused Watson's injury.

In March 2006, Wilder viewed a videotape showing an operator using the same hand to activate the locking button and the power trigger of the K2300, while holding the cutter by the rear handle in one hand. Because Watson was holding the subject saw in just this position at the time of his accident, Wilder was prompted to consider a second potential cause of Watson's accident-that Watson could have inadvertently activated the saw because of the defective placement of the trigger lock. Unbeknownst to Wilder, who viewed the video in Swedish and without a translation, the trigger lock had been deliberately disabled by the defendant's engineers so that the user in the video was activating the power cutter with only the power trigger.

Be that as it may, Wilder reenacted the accident sequence to see if the interlock on the subject saw actually prevented inadvertent activation of the saw, and found that in two separate scenarios, the interlock on the subject saw failed to prevent inadvertent activation. In the first case, it was possible while wearing work gloves [FN5], even with the saw hanging at the user's side, to depress the trigger lock and squeeze the trigger because the trigger lock is located close to the trigger on the inside of the rear handle. The second scenario in which the interlock on the subject saw did not prevent inadvertent activation was when the user reached across his body with his hand and gripped the front handle of the saw while using his other hand to grip the rear handle. The saw was forced back toward the user, driving his index finger into the "trigger lock" by a combination of the weight of the saw and the weight of the user's arm.

FN5. Although defendant suggests that there was no evidence that Watson was wearing work gloves, plaintiff will apparently testify at trial that he was.

*7 Wilder opines that recessing the trigger lock, placing a barrier over the trigger lock, or relocating the trigger lock to an area on the product that was out of reach of the operator's normal operating grip as alternative safer designs. In developing his hypothesis, Wilder looked at different models of defendant's saws and suggests that Electrolux's relocation of the trigger lock on a later model power cutter, the K3000, supports his position that the trigger lock is less likely to be inadvertently pressed in this alternative location.

Although this additional opinion was made in a letter dated March 24, 2006, well after the deadline set by this court of September 30, 2005, and only three days before his deposition of March 27, 2006, I do not find the delay disabling here. To be sure, Fed.R.Civ.P. 37(c)(1) provides when "[a] party that without substantial justification fails to disclose information required by Rule 26(a) ... is not, unless such failure is harmless, permitted to use as evidence ... any witness or information not so disclosed." Fed.R.Civ.P. 37(c)(1). Although Rule 37(c)(1) is traditionally invoked to preclude expert testimony at trial, it can also be applied to motions for summary judgment. *See Lohnes v. Level 3 Communications, Inc.*, 272 F.3d 49, 60 (1st Cir.2001) (citing *Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1007-09 (8th Cir.1998) (finding that a products liability defendant, whose summary judgment motion relied partially on the plaintiff's

lack of expert testimony, would have been significantly prejudiced by plaintiff's untimely expert disclosure). However, Rule 37(c)(1) "allows the court to admit belatedly proffered expert evidence if the proponent's failure to reveal it was either substantially justified or harmless." *Lohnes,* 272 F.3d at 60. Here, Wilder only received the video which inspired his theory on March 17. Thus, his delay until March 24, 2006, in proffering his second theory is sufficiently justified. Further, defendant, which itself sought a relaxation of the Schedule to bring the instant motions, was able to depose Wilder on his theory, and has not alleged that it has been in any way prejudiced by the late disclosure.

That Wilder was spurred to consider this alternative by a mistaken interpretation of the video does not preclude his testimony on this point. Although the trigger lock had been disabled in the video, this does not mean that one-handed activation was impossible. Indeed, Wilder was able to actuate the saw with one hand in two separate fashions, one of which was videotaped at his deposition. Thus, his Trigger Lock theory should not be precluded merely because it was stimulated by a misunderstanding.

Nonetheless, I agree with defendant that Wilder's opinion on this point is speculative. Wilder merely states in a conclusory fashion that inadvertent activation would have been prevented had the trigger lock been located elsewhere, or a barrier placed over it. However, he has done no reliable testing which would corroborate these bare assertions. Nor is there any factual basis for inferring that Watson actually caused inadvertent activation.

***8** Wilder attempts to support his theory in a redesigned model of the subject saw, the K3000. The interlock on the K3000 is located on the side rather than on the rear handle. Wilder suggests that this was a safety innovation. However, according to defendant, the interlock was moved, not for safety purposes, but because many people had trouble locating the interlock on the K2300. Defendant contends that trigger activation would if anything be *more* difficult, under the subject design than under this alternative design. Wilder has presented no evidence that the trigger lock was moved for safety reasons, or that its location on the K3000 renders it less prone to inadvertent activation, and his suggestions remain mere hypothetical concepts.

The methodology that Wilder employed is speculative and inadmissible under Federal Rule of Evidence 702. In an effort to determine how the saw could be inadvertently activated, Wilder made repeated tests with gloves on and off to see how he could activate the saw with one hand. Although Wilder was eventually able to find two different scenarios in which he could accomplish this, there is no evidence that the so-called test that he used was anything that even remotely resembled a rigorous or systematic technique.

Wilder states that a worker might become used to activating the saw with one hand, such that it becomes "instinctive" to do so. However, Wilder presents no evidence that Watson ever activated his saw in this manner, such that it might become " instinctive". Thus, Wilder's hypothesis is wholly speculative. Although Wilder was able to demonstrate at his deposition that the saw could be activated with one hand, he had to admit that his own activation of the saw was not inadvertent.

Wilder provides no evidence from which a factfinder might conclude that it is more probable than not that Watson inadvertently activated the saw. Thus, because Wilder's Trigger Lock theory is not based on a reliable methodology and requires speculation, it is insufficient to establish either a product defect or causation. I find that Wilder's testimony as to this theory must be precluded.

c. Warning

Defendant also opposes Wilder's suggestion of an information defect. In Wilder's report, he writes that if it is not possible to make a product nonhazardous without compromising its utility, then warnings and/ or training should be used to reduce the risk. Although plaintiff does not discuss an information defect in his opposition memorandum, defendant opposes allegations of any such purported defect at length.

Defendant notes that an expert's proposed opinion concerning proper warning "design" is subject to the same requirements of reliability as his opinions concerning other alleged design defects. *See generally Dhillon v. Crown Controls Corp.,* 269 F.3d 865, 870 (7th Cir.2000); *Milancowicz v. The Raymond Corp.,* 148 F.Supp.2d 525, 541 (D.N.J.2001). In order to establish the required causal connection between any failure to warn and his accident, plaintiff must prove that additional warnings on both of the suggested subjects were necessary to render the cutter reasonably safe.

***9** Because plaintiff admits that he understood that the wheel would continue to coast for "a number of seconds" after the power trigger was released, that if he contacted the wheel he could be injured, and that he therefore had to be careful to keep the cutter away from his body even when it was not under power, it is difficult to envision what type of warning would have prevented injury caused by a blade coasting down. *See Gillespie v. Sears, Roebuch & Co.,* 386 F.3d 21, 29 (1st Cir.2004); *Slate v. Bethlehem Steel Corp.,* 400 Mass. 378, 384 (1987).

The defendant's conclusory argument that the K2300 EL did not incorporate "adequate operator safety warnings" is not supported by sufficient facts or data, nor is it the product of reliable principles and methods. Indeed, it does not appear that plaintiff attempted to advance this theory at all in opposition to the motions. Nonetheless, in the interest of completeness, I conclude that the Warning theory has not been made out in the record and consequently will exclude it.

B. Summary Judgment

I now turn to the substance of the summary judgment motion and Electrolux's claim that Watson will be unable to support through reliable testimony of a qualified expert witness, that the subject power cutter was defective at the time it was sold, and that the defects alleged caused his accident and resulting injuries.

1. *Summary Judgment Review*

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Mesnick v. General Electric Co.,* 950 F.2d 816, 822 (1st Cir.1991) (internal quotation marks and citation omitted.) Summary judgment is appropriate when " the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits ... show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). A genuine issue of material fact exists when a factfinder could reasonably return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). The burden is upon the party seeking summary judgment to make a preliminary showing that no genuine issue of material fact exists. *Nat'l Amusements, Inc. v. Town of Dedham,* 43 F.3d 731, 735 (1st Cir.1995) , *cert. denied,* 515 U.S. 1103 (1995). Once the moving party has satisfied its burden, the burden shifts to the non-moving party to point to specific facts demonstrating that there is, indeed, a trialworthy issue. *Id.* The Court must view the record, and all reasonable inferences drawn therefrom, in the light most favorable to the non-moving party. *Chapman v. Bernard's Inc.,* 167 F.Supp.2d 406, 411 (D.Mass.2001) (*citing O'Connor v. Steeves,* 994 F.2d 905, 907 (1st Cir.1993)).

2. *Substantive Standards*

Because this case is before me as a result of diversity jurisdiction, and all events took place in Massachusetts, Massachusetts products liability law applies. See *Ticketmaster-New York, Inc. v. Alioto,* 26 F.3d 201, 204 (1st Cir .1994) ("[A] federal court exercising diversity jurisdiction is the functional equivalent of a state court sitting in the forum state.")

***10** Under Massachusetts law, a plaintiff challenging a product's design must show that the design was "defective" in that it presented an unreasonable risk of injury to users. *Back v. Wickes*

Corp., 375 Mass. 633, 642 (1978). Plaintiff must also prove that the defect existed at the time the product left the defendant's control. *Enrich v. Windmere Corp.,* 416 Mass. 83, 89 (1993). Whether a defect exists is partly a question of consumer expectations, and partly one of "social acceptability," involving consideration of factors such as the gravity of danger posed by the challenged design, the likelihood of harm, the technological and economic feasibility of an improved design, and adverse consequences to the product and consumer that would result from an alternative design. *Back,* 375 Mass. at 642 citing *Barker v. Lull Eng'r Co.,* 20 Cal.3d 413, 429-30 (1978). "[T]here is a case for the jury if the plaintiff can show an available design modification which would reduce the risk without undue cost or interference with the performance of the machinery. " *Uloth v. City Tank Corp.,* 376 Mass. 874, 881 (Mass.1978).

If fault lies with the manufacturer for defective design or failure to warn consumers, the manufacturer is strictly liable under Massachusetts law. Massachusetts courts "hold a manufacturer liable for defectively designed products because the manufacturer is in the best position to recognize and eliminate the design defects." *Colter v. Barber-Greene Co.,* 403 Mass. 50, 57 (1988) (citing *Solimene v. B. Grauel & Co., KG,* 399 Mass. 790, 796 (1987)). Thus, in analyzing breach of warranty of marketability claims, the focus is on the product itself rather than the actions of the plaintiff. *Cipollone,* 202 F.3d at 379.

A plaintiff who cannot establish precisely how an accident occurred is not necessarily barred from maintaining tort or warranty claims such as those asserted by Watson here, so long as he can show a greater likelihood that the accident was due to causes for which the defendant was responsible than from any other cause. *Carey v. General Motors Corp.,* 377 Mass. 736, 740 (1979).

3. *Analysis*

Here, parties dispute whether the lack of a blade brake and/or the location of the trigger lock render the saw defective. Wilder opines that to a reasonable degree of engineering certainty, Watson's injury could have been prevented or mitigated by the incorporation of either or both a blade brake mechanism and an effective interlock into the design of the K2300.

Because Wilder may only testify as to the Blade Brake theory, Watson will have the burden of proving by the preponderance of the evidence that " there was a greater likelihood or probability that the harm complained of was due to causes for which the defendant was responsible than from any other cause." *Carey,* 377 Mass. at 740. Thus, Watson must prove by a preponderance of the evidence that the absence of a blade brake rendered the product defective and caused his injury.

***11** I find plaintiff has satisfied his burden by showing an "available design modification [the addition of a blade brake] which would reduce the risk without undue cost or interference with the performance of the machinery." *Uloth,* 376 Mass. at 881. Wilder has suggested the addition of a brake that he contended would ensure that the product was safer for users. This modification would not have unduly increased its cost, and defendant has offered no evidence showing that it would impair its utility. Thus, there is a sufficient basis for a reasonable factfinder to find the existence of a product defect.

Moreover, there is sufficient evidence to show causation. Wilder can testify that the absence of a blade brake extended the coast down time sufficiently for a jury to find that but for this extended time the injury would not have occurred. The focus in a breach of warranty case is on the product itself. At this stage in the proceedings, no reasonable cause for the injury has been advanced, other than the Blade Brake theory of product misdesign (and perhaps contributory negligence by Watson, effectively an immaterial cause in a breach of warranty context), which would lead to the injury.

III. CONCLUSION

For the reasons set forth above, Electrolux's motion to exclude the expert's opinion is GRANTED as to

the Trigger Lock and Warning theories and DENIED as to the Blade Brake theory. As a consequence, Electrolux's motion for Summary Judgment is GRANTED as to the Trigger Lock and Warning theories and DENIED as to the Blade Brake theory.

D.Mass.,2006.
Watson v. Electrolux Professional Outdoor Products, Inc.
Slip Copy, 2006 WL 2246416 (D.Mass.)

END OF DOCUMENT

Exhibit 5

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,

Defendants.

CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

DAY 1 OF 2

DEPOSITION OF DR. DAVID S. BROOKSTEIN

Philadelphia, Pennsylvania

July 26, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

it was something made from polyglycolic acid, but I'm not sure. And as part of Albany International Research Company, we had a fiber spinning group, and Matt Hermes and a few other people from U.S. Surgical had approached Albany to spin the -- make this fiber, and then when the fiber was made, they said, Well, let's talk to the guy who runs biomedical devices and see if we can make sutures. 08:46:54a 08:46:59a 08:47:00a 08:47:04a 08:47:06a 08:47:09a 08:47:12a 08:47:14a 08:47:17a

So I then worked with Hermes and other people who I don't recall at U.S. Surgical to come up with a braided structure. 08:47:18a 08:47:20a 08:47:23a

Q. That's because you were an expert on braiding? 08:47:30a 08:47:31a

A. I assume that's why they came to me. 08:47:32a

Q. Right. Beyond -- how long did that project last? 08:47:35a 08:47:47a

A. I don't recall. That was -- 08:47:48a

Q. Can you give me any sort of an approximation? 08:47:50a 08:47:52a

A. Two, three years. But, you know, I want to be able to -- if this becomes important, I want to be able to go back and look. I -- this is over 15 years ago. I don't -- over almost 20 years ago, I don't recall. We had many projects. 08:47:52a 08:47:54a 08:47:57a 08:48:00a 08:48:04a

to assume? 11:04:49a

A. For the literal, yes. 11:04:50a

Q. For purposes of literal infringement? 11:04:51a

A. Mm-hmm. 11:04:53a

Q. Okay. 11:04:55a

MR. SABER: Why don't we take a 11:04:55a
little break right now. 11:04:57a

MR. BONELLA: Okay. 11:06:06a

THE WITNESS: Mm-hmm. 11:06:06a

(A recess was had from 11:04 11:06:06a
A.M. to 11:15 A.M.; and then the proceedings 11:06:06a
continued as follows:) 11:06:06a

THE VIDEOGRAPHER: The time is 11:15:49a
11:15; we are back on the video record. 11:15:50a

BY MR. SABER: 11:15:53a

Q. Dr. Brookstein, I want to just ask you 11:15:53a
a question or two about your experience on 11:15:55a
sutures as it relates to coating. 11:15:58a

Have you been -- had specific 11:16:01a
experience on issues related to the coating of 11:16:04a
sutures? 11:16:09a

A. In the work we did for U.S. Surgical, 11:16:11a
I can't recall if we coated it or not, so I can't 11:16:13a
answer that. I mean, as I said, my primary 11:16:18a
actual hands-on work with sutures, not studying 11:16:20a

about sutures, but actually designing and developing and the quality associated with that was for U.S. Surgical; I don't recall if we coated or not. 11:16:23a 11:16:25a 11:16:32a 11:16:34a

Q. You just don't remember from that project? 11:16:35a 11:16:38a

A. Right. 11:16:38a

Q. Do you recall whether you've had any experience with respect to coating of sutures in your background prior to your work on this case? 11:16:38a 11:16:40a 11:16:44a

A. I don't recall, because, you know, we looked at the vascular prosthesis patent that had sutures on it, I don't recall if they were coated or not. I don't know. 11:16:49a 11:16:51a 11:16:53a 11:16:56a

Q. Have you -- do you recall whether you have had any experience with respect to what coating -- how coating impacts on suture properties? 11:16:58a 11:17:01a 11:17:08a 11:17:11a

A. Well, I've looked at the Gitis report and tried to -- 11:17:15a 11:17:19a

Q. I'm sorry, prior to your work in this case. 11:17:20a 11:17:21a

A. Not prior to the work in this case. 11:17:22a

Q. Okay. The -- would it be correct to say that what you've learned about coating and 11:17:23a 11:17:31a

its impact on suture properties is in conjunction with your work on this case? 11:17:33a 11:17:35a

A. That would be proper to say that, yes. 11:17:38a

Q. The -- do you have an opinion as to whether it is generally well-known in the suture art that coating multifilament suture improves the tactile smoothless -- smoothness, pliability, and knot tie-down performance of that suture? 11:17:44a 11:17:45a 11:17:48a 11:17:53a 11:17:58a

A. That's a long question. Do that -- let's do that slower and -- 11:18:02a 11:18:05a

Q. Sure, I'll even try to take it into parts. 11:18:06a 11:18:09a

A. Yeah. 11:18:09a

Q. Do you have an opinion -- well, let me ask you this. Is it correct that it is generally known in the suture art that coating a multifilament suture improves the tactile smoothness of the suture? 11:18:09a 11:18:12a 11:18:14a 11:18:16a 11:18:18a

MR. BONELLA: Objection; incomplete hypothetical. 11:18:22a 11:18:23a

THE WITNESS: I haven't seen anything that says that. 11:18:24a 11:18:25a

BY MR. SABER: 11:18:26a

Q. You don't have an opinion one way or the other? 11:18:26a 11:18:28a

A. I have no opinion on that. 11:18:28a
Q. Do you know whether it is generally 11:18:29a
known in the suture art that coating a 11:18:31a
multifilament suture improves the pliability of 11:18:35a
that suture? 11:18:39a
MR. BONELLA: Objection; incomplete 11:18:40a
hypothetical. 11:18:41a
THE WITNESS: Yeah, I've seen 11:18:42a
nothing like that. I can't judge that. 11:18:43a
BY MR. SABER: 11:18:45a
Q. You have no opinion one way or the 11:18:45a
other? 11:18:47a
A. I have an opinion that coating only 11:18:47a
affects in a minor way the handleability. 11:18:49a
Q. Okay. 11:18:52a
A. That's it. 11:18:52a
Q. Okay. Well, let me -- what do you 11:18:52a
mean when you say handleability? 11:18:55a
A. You know, if the guy does this 11:18:56a
(indicating) and says it feels smooth, then 11:18:58a
that's all. And even that from what I've read in 11:19:00a
some of your experts' reports, like Burks', even 11:19:06a
that is almost imperceptible. 11:19:09a
Q. Is it -- do you agree that it is 11:19:16a
generally known in the suture art that coating a 11:19:20a

multifilament suture improves the knot tie-down performance of that suture? 11:19:22a 11:19:25a

MR. BONELLA: Objection; incomplete hypothetical. 11:19:27a 11:19:29a

THE WITNESS: I've seen no evidence where that's discussed. 11:19:29a 11:19:31a

BY MR. SABER: 11:19:33a

Q. So you don't have an opinion one way or the other? 11:19:33a 11:19:37a

MR. BONELLA: Objection; incomplete -- 11:19:37a 11:19:38a

BY MR. SABER: 11:19:39a

Q. Is that correct? 11:19:39a

MR. BONELLA: Incomplete hypothetical on that previous question. 11:19:40a 11:19:41a

THE WITNESS: My opinion is that coating only has an immaterial effect that might -- might -- affect handleability, and that's all. 11:19:43a 11:19:43a 11:19:47a 11:19:51a

BY MR. SABER: 11:19:51a

Q. What is that opinion based on? 11:19:51a

A. It's based mostly on some of the work I've read from Gitis. It's an opinion of looking at the micrographs that I took and seeing the level of coating that was on those sutures. It's 11:19:53a 11:19:55a 11:19:59a 11:20:02a

BY MR. SABER: 11:22:20a

Q. Right. Let me show you what has been marked as Defendant's Exhibit-202. And have you ever seen this document? 11:22:20a 11:22:22a 11:22:27a

A. No, I've never seen this document. 11:22:28a

Q. Did you ever try to review the patent literature on coating of sutures in connection with rendering opinions in this case? 11:22:29a 11:22:37a 11:22:39a

A. I don't recall looking at other patents, no. 11:22:47a 11:22:50a

Q. Did you review the exhibits to Dr. Mukherjee's reports? 11:22:50a 11:22:53a

A. Yes. 11:22:54a

Q. Do you understand -- 11:22:54a

A. If I -- if I said in my report I did, I did. I mean, I don't -- I read Mukherjee's report. Sometimes I didn't go back and look at the exhibits because it wasn't an area that I was concerned in, but if it was an area of concern that I was in and then I responded in my rebuttal and I said going back to this, yes. 11:22:56a 11:23:00a 11:23:04a 11:23:06a 11:23:10a 11:23:11a 11:23:13a

Q. Do you recall whether this exhibit, Defendant's Exhibit-202, was one of the exhibits -- 11:23:18a 11:23:19a 11:23:21a

A. No. 11:23:21a

Q. Go ahead. Go ahead. 11:25:39a
A. As you know, in any patent nothing 11:25:39a
stands by itself. There's a reason -- there's a 11:25:42a
story it's trying to tell, it's trying to teach. 11:25:45a
Okay? I am not going to sit here today and be 11:25:47a
making comments about patents that I haven't seen 11:25:51a
unless I've had the proper time to study them, 11:25:53a
study the context that they're in. Once I've 11:25:56a
done that, I'll be more than happy to answer your 11:25:58a
question, but I'm not going to do that. 11:26:01a
Q. Okay. Now, if in fact this was an 11:26:02a
exhibit to Dr. Mukherjee's report, you had that 11:26:06a
opportunity, didn't you? 11:26:08a
MR. BONELLA: Object to the form 11:26:12a
of the question. 11:26:12a
BY MR. SABER: 11:26:13a
Q. You had the opportunity to study it if 11:26:13a
it were an exhibit, correct? 11:26:15a
A. If it were an exhibit and I said I 11:26:16a
read it, I would have had the opportunity, that's 11:26:19a
correct. 11:26:20a
Q. Again, I just want to make sure the 11:26:21a
record is clear. Do you disagree that a 11:26:25a
multifilament suture typically requires a surface 11:26:30a
coating to improve the tactile smoothness, 11:26:33a

on patents that I have not seen before. Whether it was in Mukherjee's thing or not, I have not seen this before and I cannot do that and will not do that. 11:27:13a 11:27:15a 11:27:18a 11:27:20a

Q. Okay. Could you look at the first page here? 11:27:25a 11:27:27a

A. The cover? 11:27:29a

Q. Yes, sir. 11:27:31a

A. Okay, yes. 11:27:31a

Q. Yes, sir. 11:27:32a

Do you see the assignee is Ethicon, Inc.? 11:27:32a 11:27:38a

A. Yes, I do. 11:27:39a

Q. Do you have any reason to believe that Ethicon, Inc., would be providing statements in the -- in its patent that it didn't believe to be true? 11:27:39a 11:27:41a 11:27:46a 11:27:47a

A. I have no idea how Ethicon -- 11:27:47a

MR. BONELLA: Objection. Argumentative. 11:27:47a 11:27:48a

THE WITNESS: I have no idea how Ethicon's business practices are. How would I know? 11:27:48a 11:27:50a 11:27:52a

BY MR. SABER: 11:27:52a

Q. The assignee listed on the '446 patent 11:27:52a

is Ethicon, Inc., isn't that correct? 11:27:55a
A. That's correct. 11:27:57a
Q. All right. The -- do you see one of the inventors is Mr. Alastair Hunter? 11:27:58a 11:28:01a
A. I do. 11:28:05a
Q. Do you have an understanding as to whether Mr. Alastair Hunter is also one of the inventors on the '446 patent? 11:28:06a 11:28:07a 11:28:10a
A. He is. 11:28:13a
(Whereupon a document was marked, for identification purposes, as Defendant's Exhibit-203.) 11:28:54a 11:28:54a 11:28:54a
BY MR. SABER: 11:29:05a
Q. Sir, let me show you what's been marked as Defendant's Exhibit-203. 11:29:05a 11:29:06a
A. Mm-hmm. 11:29:09a
Q. Have you ever seen this patent before, sir? 11:29:09a 11:29:11a
A. I don't recall seeing this. 11:29:11a
Q. Do you know whether this was one of the exhibits to Dr. Mukherjee's reports? 11:29:12a 11:29:14a
A. I don't know. 11:29:16a
Q. If it was an exhibit to Dr. Mukherjee's report, would you agree with me you had the opportunity to review it? 11:29:17a 11:29:20a 11:29:22a

A. If it was an exhibit to Dr. Mukherjee's report, I did have the opportunity to review it. 11:29:23a 11:29:24a 11:29:26a

Q. But you don't recall ever seeing this? 11:29:27a

A. I don't recall seeing this. 11:29:29a

MR. BONELLA: Objection. That's not what his testimony said before. It mischaracterizes his testimony. 11:29:30a 11:29:31a 11:29:33a

BY MR. SABER: 11:29:35a

Q. Could you turn to -- well, again, this is a -- on the first page, this is a patent that was assigned to Ethicon, Inc., isn't that correct? 11:29:35a 11:29:38a 11:29:41a 11:29:43a

A. That is correct. 11:29:43a

Q. Same as the '446 patent? 11:29:44a

MR. BONELLA: I'm going to object to the form of the question. 11:29:47a 11:29:48a

BY MR. SABER: 11:29:49a

Q. Is that correct? 11:29:49a

MR. BONELLA: Object to the form of the question. 11:29:52a 11:29:52a

THE WITNESS: What is the same? 11:29:52a

BY MR. SABER: 11:29:52a

Q. That the '446 -- well, strike that. 11:29:52a

Do you see one of the inventors 11:29:54a

Argumentative. 11:32:39a

THE WITNESS: I don't know how they conduct their business. I don't know how they conduct their business. I've never talked to people at Ethicon. 11:32:40a 11:32:41a 11:32:43a 11:32:46a

MR. SABER: Mark this as 204. 11:33:11a

(Whereupon a document was marked, for identification purposes, as Defendant's Exhibit-204.) 11:33:11a 11:33:11a 11:33:12a

BY MR. SABER: 11:33:14a

Q. Let me show you what's been marked as Defendant's Exhibit-204 and ask you if you've had an opportunity -- have you seen this document before? 11:33:14a 11:33:22a 11:33:28a 11:33:29a

A. I do not recall seeing this document before. 11:33:29a 11:33:30a

Q. Do you know whether this was an exhibit to Dr. Mukherjee's report? 11:33:31a 11:33:33a

A. I don't recall either way. 11:33:35a

Q. If it were an exhibit to Dr. Mukherjee's report, would you agree with me that you had the opportunity to review this document? 11:33:37a 11:33:38a 11:33:40a 11:33:42a

A. If it were in Dr. Mukherjee's report that I read, I would have had the opportunity to 11:33:43a 11:33:46a

read it. I agree. 11:33:48a

Q. Do you see in the first column 11:33:56a

starting at about Line 43 -- 11:34:08a

A. Mm-hmm. 11:34:10a

Q. -- where it says, Such multifilament 11:34:10a

sutures generally -- excuse me. Such 11:34:13a

multifilament sutures exhibit a certain degree of 11:34:15a

undesirable roughness or grabbiness in what has 11:34:18a

been determined -- what has been termed their, 11:34:23a

quote, tie-down, closed quote, performance; i.e., 11:34:26a

the ease or difficulty of sliding a knot down the 11:34:29a

suture into place, or the ease of snugging a 11:34:33a

square knot in place? 11:34:36a

A. I do. 11:34:39a

Q. Do you agree with that sentence? 11:34:40a

MR. BONELLA: Object to the form 11:34:41a

of the question. The sentence says, Such 11:34:41a

multifilament sutures. You didn't even read 11:34:44a

what the heck it's talking about. I mean, it's 11:34:46a

a totally unfair question. 11:34:48a

THE WITNESS: That sentence -- I 11:34:49a

have several responses. One, I'm going to come 11:34:51a

back to what I said earlier on the last two 11:34:53a

patents you asked me to look at: I cannot and 11:34:56a

will not opine on a patent that I have not read 11:34:58a

A. (Witness reviewing document.) Okay. 11:50:37a
Q. Do you understand this to be 11:51:06a
directions for use? 11:51:07a
A. I wouldn't call this directions for 11:51:08a
use. I would call it important product 11:51:09a
information. It has elements of directions for 11:51:12a
use in it, but it's -- it seems to be broad and 11:51:15a
just mention some things about the use. 11:51:18a
Q. Do you understand that this is a copy 11:51:20a
of material that's included in what FiberWire 11:51:22a
sold? 11:51:27a
A. I don't know how FiberWire is sold. 11:51:27a
Q. Do you see in the first paragraph -- I 11:51:29a
want to look at the English part of this. It's 11:51:31a
in -- obviously it's in several languages, but 11:51:35a
let's focus on the English part. 11:51:35a
Do you see in the first paragraph 11:51:38a
about two-thirds of the way down the sentence 11:51:38a
that says, The coating acts as a lubricant for 11:51:40a
suture sliding, knot tying, and ease of passing 11:51:44a
suture through tissue? 11:51:47a
A. I see that sentence. 11:51:48a
Q. Do you have any reason to disagree 11:51:50a
with that sentence? 11:51:52a
A. I have not analyzed -- I have not 11:51:53a

measured FiberWire -- I have not measured FiberWire properties to see how the coating acts. 11:51:57a 11:52:00a

Q. Do you have any evidence to disagree with the statement that Arthrex makes about FiberWire? 11:52:04a 11:52:07a 11:52:13a

A. The only evidence that I have is -- 11:52:14a

Q. The statement about coating. 11:52:15a

A. Right. The only evidence that I have is the evidence that is in the Gitis report, and I have problems with the Gitis report, which I'm sure we'll discuss today. 11:52:17a 11:52:18a 11:52:22a 11:52:25a

Q. Okay. Beyond that, do you have any evidence to disagree with this statement? 11:52:27a 11:52:29a

A. I don't -- I don't recall. 11:52:33a

Q. Okay. Have you done any tests on FiberWire to determine the effect of coating? 11:52:35a 11:52:42a

A. I have measured the amount of coating and I have taken micrographs to see how the coating is distributed within the cross-section, those are the two tests I've done. 11:52:47a 11:52:49a 11:52:52a 11:52:55a

Q. That's what you've done? 11:52:56a

A. That's what I've done. 11:52:57a

Q. Have you done any other tests? 11:52:58a

A. I have not done any other tests. 11:52:59a

Q. Have you done any other analysis of 11:53:01a

the amount of coating that's on them. 11:53:56a

Q. Right, that you talked about in your report? 11:53:58a 11:53:59a

A. Right, that's the only test that I've ever been asked to do. 11:53:59a 11:54:02a

Q. Okay. Do you know whether DePuy-Mitek or Ethicon has ever done any tests on the effect of coating on the FiberWire suture? 11:54:03a 11:54:05a 11:54:09a

A. I have no way of knowing that. 11:54:11a

Q. Did you ever ask whether any such tests were done? 11:54:13a 11:54:15a

A. No. 11:54:16a

Q. Were you ever told that any such tests were done? 11:54:17a 11:54:20a

A. I don't recall. 11:54:22a

Q. Do you -- you don't...? 11:54:23a

A. I don't recall being asked. 11:54:25a

Q. No, do you -- have you ever discussed the topic of whether DePuy-Mitek or Ethicon has done any testing of the effect of coating on the FiberWire product? 11:54:27a 11:54:29a 11:54:34a 11:54:39a

A. No. 11:54:40a

Q. Would that be information that you would like to review, if it exists? 11:54:41a 11:54:42a

A. No, because I had the Gitis 11:54:44a

information, I didn't think it was necessary. 11:54:46a
Q. You don't think it's important if 11:54:48a
Ethicon or DePuy-Mitek has done tests on the 11:54:50a
effect of coating? 11:54:52a
A. I think it's better to see what Gitis 11:54:53a
did. 11:54:56a
Q. Sir, could you answer my question? 11:54:56a
A. Yeah. Yes. 11:54:57a
MR. SABER: Could you read back 11:54:59a
my question. 11:55:00a
THE WITNESS: Yeah, could you 11:55:02a
read it back? I don't remember the question. 11:55:03a
MR. SABER: I know, that's why 11:55:04a
I'm asking. 11:55:05a
THE WITNESS: I thought you were 11:55:06a
looking at me, that I should read it back. 11:55:06a
(The court reporter read the 11:55:08a
record as follows: 11:55:08a
"QUESTION: You don't think it's 11:55:08a
important if Ethicon or DePuy-Mitek has done 11:55:08a
tests on the effect of coating?") 11:55:08a
THE WITNESS: Important to what? 11:55:34a
BY MR. SABER: 11:55:36a
Q. To your opinions in this case. 11:55:36a
A. No, I do not think it's important. 11:55:46a

Q. Why not? 11:55:49a
A. Because the -- to go back to my 11:55:50a
reports, but this case is about two intersecting 11:55:51a
-- intertwining sets of yarns that are 11:55:55a
non-bioabsorbable, one comes from one set, one 11:55:58a
comes from another set, they have certain 11:56:03a
functions they do. 11:56:04a
The coating is really just a -- 11:56:05a
it doesn't affect what the -- what this patent 11:56:08a
is trying to teach. It's something you can 11:56:10a
coat, you cannot coat, but that's not what 11:56:12a
this patent is about. This patent is not 11:56:14a
about coating. 11:56:16a
Q. So in your opinion, if Ethicon has 11:56:16a
tests talking about the effect of coating on the 11:56:19a
FiberWire product, that would be unimportant to 11:56:22a
you? 11:56:25a
A. If Ethicon has? 11:56:26a
Q. Yes, sir, or DePuy-Mitek. 11:56:30a
A. In the context of this patent? 11:56:31a
Q. In the context -- yeah, for the 11:56:34a
purposes of rendering your opinions in this 11:56:37a
case. 11:56:39a
A. For the purposes of rendering this 11:56:39a
opinion -- 11:56:40a

Q. Any of your opinions in this case. 11:56:41a
A. -- on this case associated with the 11:56:42a
'446. It means nothing to me about the coating 11:56:43a
because the coating is not what this patent is 11:56:47a
about. 11:56:49a
Q. Is the test that anyone has done on 11:56:49a
coating, is that important to your opinions in 11:56:52a
this case? 11:56:55a
MR. BONELLA: Object to the form 11:56:57a
of the question. 11:56:57a
THE WITNESS: Well, I wanted to 11:56:58a
see what Gitis had to say about it, yes, because 11:57:00a
he offered some opinions on it and I wanted to 11:57:05a
see what he said. 11:57:07a
BY MR. SABER: 11:57:07a
Q. So you think that Dr. Gitis's opinions 11:57:07a
of tests are important to your opinions in this 11:57:09a
case, is that correct? 11:57:11a
A. No, I want to see how Dr. Gitis did 11:57:13a
his work. 11:57:17a
Q. Do you think that Dr. -- assume with 11:57:17a
me -- I know you have some issues with 11:57:19a
Dr. Gitis's test. 11:57:21a
A. Mm-hmm. 11:57:22a
Q. But I want to make sure I understand 11:57:23a

Exhibit 6

US005147383A

United States Patent [19]

Bezwada et al.

[11] Patent Number: 5,147,383

[45] Date of Patent: Sep. 15, 1992

[54] SUTURE COATED WITH A POLYVINYL ESTER

[75] Inventors: **Rao S. Bezwada**, Whitehouse Station; **Alastair W. Hunter**, Bridgewater, both of N.J.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **792,321**

[22] Filed: **Nov. 12, 1991**

Related U.S. Application Data

[62] Division of Ser. No. 473,505, Feb. 1, 1990, Pat. No. 5,089,013.

[51] **Int. Cl.**[5] **A61L 17/00**

[52] **U.S. Cl.** **606/231**; 606/228

[58] **Field of Search** 606/228, 231, 230

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Assistant Examiner—Jeffrey A. Schmidt
Attorney, Agent, or Firm—Matthew S. Goodwin

[57] **ABSTRACT**

A surgical suture having a coating thereon of at least one polyvinyl ester, and a method for improving the knot tiedown performance of a suture by first coating a polyvinyl ester solution onto the surface of the suture and then removing the solvent from the coated suture.

11 Claims, No Drawings

SUTURE COATED WITH A POLYVINYL ESTER

This is a division of application Ser. No. 473,505, filed Feb. 1, 1990, U.S. Pat. No. 5,089,013.

BACKGROUND OF THE INVENTION

This invention relates to coated surgical sutures. More specifically, it relates to sutures coated with a vinyl polymer and to a method for improving the knot tiedown performance of a surgical suture.

Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown Performance of the suture, so it passes easily and smoothly through tissue during operative procedures. A monofilament suture may also require a surface coating to reduce the stiff feel of the suture and to increase its pliability.

In response to the need for suitable coatings for surgical sutures, numerous patents have disclosed potential coating compositions. U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,105,034 discloses a multifilament suture coating of a poly(alkylene oxalate), e.g. poly(hexamethylene oxalate). Although the coating compositions disclosed in these patents exhibit excellent handling characteristics and enhance many of the properties of the coated suture, the knot integrity of the coated suture diminishes slightly.

U.S. Pat. No. 3,527,650 discloses a coating of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although PTFE acts as an excellent lubricant to decrease the roughness of multifilament sutures, it has a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application. U.S. Pat. No. 4,043,344 discloses a PLURONICS TM ethylene oxide/propylene oxide copolymer coating for nonabsorbable surgical sutures. Unfortunately, these copolymer coatings lose their lubricity during wet tiedown evaluations.

In view of the deficiencies with the potential candidates for suture coatings, it would be desirable to develop a coating for a suture that can be applied using conventional techniques, that increases the tactile smoothness of the coated suture without sacrificing its physical properties, and that does not adversely affect the knot integrity of the suture.

SUMMARY OF THE INVENTION

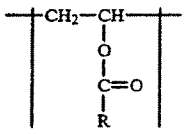
In one aspect, the invention is a suture having its surface coated with an amount of at least one polyvinyl ester effective to improve its knot tiedown performance relative to the knot tiedown performance of the uncoated suture.

In another aspect, the invention is a method of improving the knot tiedown performance of a suture. This method comprises the steps of coating the surface of the suture with an effective amount of a solution of at least one polyvinyl ester in an organic solvent, and then removing the solvent from the coated suture.

The polyvinyl ester coating of this invention can be applied to the surface of a suture using conventional techniques. The knot tiedown performance of the coated suture, which is an indication of its tactile smoothness, dramatically improves without sacrificing the tensile properties of the coated suture. Surprisingly, these improvements in properties are acheived without adversely affecting the knot security of the coated suture.

DETAILED DESCRIPTION OF THE INVENTION

Polyvinyl (Pv) esters within the scope of this invention are known and can be prepared by conventional techniques, for example, by polymerizing a vinyl ester monomer using a free radical initiation process. Preferably, the PV ester is represented by repeating units of the formula:



wherein R is C_{6-30} straight or branched alkyl.

If the alkyl group of the formula above were to have less than 10 carbons, then the ester would not typically exhibit good coating properties. If the alkyl group were to have greater than 30 carbons, then the availability and purity of the ester would typically not be desirable for coating applications Preferably, R is C_{14-18} straight alkyl. The most preferred PV ester is polyvinyl stearate.

The amount of PV ester coated onto the surface of the suture to improve knot tiedown performance will generally depend on the molecular weight of the PV ester and can readily be determined empirically. In most instances, the required amount of PV ester decreases as its molecular weight increases. Advantageously, the amount of PV ester coated onto the suture ranges from about 0.3 to about 20, preferably from about 0.5 to about 15 percent of the weight of the coated suture. Generally, amounts greater than 20 weight percent may compromise the knot security of the coated suture and amounts below 0.3 weight percent may fail to achieve any significant improvement in suture properties. The suture can be coated with not only one PV ester, but also a mixture of 2 or more PV esters, if desired. Preferably, the suture is coated with one PV ester.

The PV ester coatings of this invention are typically characterized by a weight average molecular weight as determined by gel permeation chromatography ranging from about 50,000 to about 2,000,000, preferably from about 100,000 to about 1,000,000, and most perferably from about 200,000 to about 500,000. A PV ester with molecular weight below 50,000 may fail to significantly improve the knot tiedown of a coated suture, and a PV ester with molecular weight above 2,000,000 may increase the stiffness of the coated suture.

Sutures within the scope of this invention can be of any type used or contemplated for operative procedures. The suture can be synthetic or natural, absorbable or nonabsorbable, or a monofilament or multifilament in a braided, twisted or covered form. In addition, the sutures can be attached to one or more needles, if desired. Examples of absorbable monofilament sutures include natural sutures such as surgical gut and collagen, and synthetic sutures such as homopolymers and copolymers of p-dioxanone. Examples of absorbable multifilament sutures include sutures prepared from polymers of one or more lactones, e.g. VICRYL ®

poly(lactide-co-glycolide) multifilament suture. Examples of nonabsorbable monofilament and multifilament sutures include nylon, polypropylene, steel, polyvinylidene fluoride, linen, cotton, silk, and polyesters such as polyethylene terephthalate (PET). The preferred sutures are nonabsorbable, multifilament sutures, preferably polyester sutures. The most preferred suture is PET.

The organic solvent for the PV ester coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane and aromatic solvents such as toluene.

The coating can easily be prepared by simply dissolving the PV ester into the appropriate organic solvent. The concentration of the ester in solution will, of course, depend on the amount of PV ester desirably coated onto the surface of the suture, but generally should range from about 3 to about 20, preferably from about 5 to about 15 weight percent.

Once a solution of the PV ester is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temperature under vacuum.

The organic solvent and the preparation of a coating solution for application is normally required for coating multifilament sutures. However, an alternative approach is feasible for coating monofilament sutures without requiring the preparation of coating solution. If a synthetic monofilament suture is to be coated, then the fiber-forming polymer from which the suture is derived could be coextruded with a suitably low molecular weight PV ester so that the ester could exude to the surface of the fiber during extrusion to increase its tactile smoothness. Such methods have been demonstrated to enhance the lubricity and knotting characteristics of the fiber-forming polymer.

The PV ester in preferred embodiments of this invention is an essentially nonabsorbable, water insoluble, waxy solid. However, the ester can be modified or additives can be incorporated into the coating composition to tailor coating properties for specific applications. For example, the ester can be made water soluble by copolymerizing the ester with a polyvinyl alcohol and/or polyvinyl pyrrolidone. Alternatively, a vinyl alcohol ester could be copolymerized with vinyl alcohol and/or vinyl pyrrolidone. A bioabsorbable ester especially suited for absorbable sutures can be prepared by first functionalizing a low molecular weight PV ester, and then copolymerizing it with one or more lactones, e.g. glycolide, e-caprolactone, lactide, p-dioxanone, and the like. Similarly, silicone lubricating agents such as polydimethylsiloxane resins and elastomers, as well as other known polymeric coatings such as homopolymers and copolymers of p-dioxanone and PLURONICS TM ethylene oxide/propylene oxide copolymers, can be added to the coating composition to modify or enhance the final properties of the coated suture. All of these embodiments, as well as similar embodiments to modify or enhance the coated suture properties, are well within the scope of the claimed invention.

Although the PV ester has been described as a coating for surgical sutures, noncoating applications can be readily envisioned. For example, the PV ester may be used as a slip agent in thermo-dye transfer processes, as an elastomeric component for polyester molding compounds for bumpers and dashboards of automobiles, as a component in tissue adhesives for dentistry and surgery and as a component in jet printing ink applications.

The following example illustrates but is in no way intended to limit the scope of the claimed invention. In the example, the tensile properties, tiedown roughness and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. The straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The tiedown roughness is a measure of the knot tiedown performance. It provides an indication of the force required to slide a knot down a suture, and it is determined generally according to the procedure described in U.S. Pat. No. 3,942,532. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping.

EXAMPLE

For each of three runs, a solution of polyvinyl stearate with a weight average molecular weight of 239,000 and a melting temperature of 48° C. in toluene is prepared. A size 2/0 (USP standard) MERSILENE ® PET braided multifilament suture is coated at room temperature with the coating solution using conventional laboratory coating equipment, and the coated suture is subsequently dried in air at 110° F. to remove the toluene. Table 1 compares the tensile and tiedown roughness properties and the knot security characteristics for each of the three runs with an uncoated MERSILENCE ® PET braided multifilament suture.

TABLE 1

PROPERTIES OF POLYESTER SUTURE COATED WITH POLYVINYL STEARATE (PVS)

	PVS COATING CONCENTRATION IN TOLUENE, WT. PERCENT			UNCOATED SUTURE
	5.15	8.10	12.15	CONTROL
Percent Solids[1], wt.	0.97	1.74	5.20	—
Suture Diameter, mils.	13.60	13.64	13.93	13.23
Dry Tiedown Roughness, gms.	140.4	127.8	118.6	355.5
Wet[2] Tiedown Roughness, gms.	126.2	135.4	137.1	249.2
Wet Knot Security	4	4	4	4
Dry Knot Tensile Strength, psi	52,567	51,973	50,232	52,458
Wet Knot Tensile Strength, psi	53,971	54,452	48,832	56,794
Dry Straight Tensile Strength, psi	94,882	94,235	91,994	102,946
Percent Elongation	14.70	15.00	16.30	16.27

[1]Determined by measuring the difference in weight between the coated and uncoated suture.
[2]Wet properties are determined after soaking the suture in water at 25° C. for at least 24 hours.

The results indicate that the polyester suture coated with a varying amount of Polyvinyl stearate exhibits significantly improved dry and wet tiedown roughness relative to that of the uncoated suture. The improved roughness is acheived without sacrificing knot security or the tensile properties of the uncoated suture. Gener-

ally, a wet tiedown roughness of less than 200 grams, preferably less than 150 grams, for the coated sutures of this invention can be readily obtained.

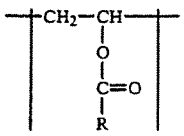
Similar outstanding results can be obtained with other PV ester coatings within the scope of the claimed invention.

We claim:

1. A suture wherein the outer surface thereof is coated with at least one homopolymer of a vinyl ester monomer in an amount between about 0.3 to about 20 percent of the weight of the coated suture.

2. The suture of claim 1 wherein the surface thereof is coated with one homopolymer of a vinyl ester monomer.

3. The suture of claim 2 wherein the homopolymer is represented by repeating units of the formula:



where R is C_{6-30} straight or branched alkyl.

4. The suture of claim 3 wherein R is C_{14-18} straight alkyl.

5. The suture of claim 4 wherein the homopolymer is polyvinyl steasrate.

6. The issue of claim 5 wherein the molecular weight of the homopolymer is between about 200,00 and about 500,000.

7. The suture of claim 6 wherein the he suture is a monofilament or multifilament suture with or without one or more needles.

8. The suture of claim 7 wherein the he suture is a multifilament suture.

9. The suture of claim 8 wherein he multifilament suture is an nonabsorbable suture.

10. The suture of claim 9 wherein the he suture is a polyester.

11. The suture of claim 10 wherein the polyester is polyethylene terephthalate.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,147,383

DATED : September 15, 1992

INVENTOR(S) : Rao S. Bezwada and Alastair W. Hunter

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 6:

In claim 5 "steasrate" should be -- stearate --.

In claim 6, "issue" should be -- suture --.

In claim 7, "he" should be eliminated.

In claim 8, "he" should be eliminated.

In claim 9, "he" should be -- the --.

In claim 10, "he" should be eliminated.

Signed and Sealed this

Nineteenth Day of October, 1993

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

Exhibit 7

US005089013A

United States Patent [19]

Bezwada et al.

[11] Patent Number: 5,089,013

[45] Date of Patent: Feb. 18, 1992

[54] **SUTURE COATED WITH A POLYVINYL ESTER**

[75] Inventors: **Rao S. Bezwada**, Whitehouse Station; **Alastair W. Hunter**, Bridgewater, both of N.J.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **473,505**

[22] Filed: **Feb. 1, 1990**

[51] **Int. Cl.**[5] **A61L 17/00**; A01N 1/02; A61K 1/02

[52] **U.S. Cl.** **606/228**; 606/231; 427/2

[58] **Field of Search** 606/228, 229, 230, 231; 427/2; 623/5; 604/368

[56] **References Cited**

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3,607,848	9/1971	Stoy et al.	623/66 X
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4,027,676	6/1977	Mattei	606/231 X
4,034,344	8/1977	Landi et al. .	
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4,693,939	9/1987	Ofstead	623/5 X
4,711,241	12/1987	Lehmann .	
4,844,067	7/1989	Ikada et al.	427/2 X

Primary Examiner—David J. Isabella
Assistant Examiner—Elizabeth M. Burke
Attorney, Agent, or Firm—Matthew S. Goodwin

[57] **ABSTRACT**

A surgical suture having a coating thereon of at least one polyvinyl ester, and a method for improving the knot tiedown performance of a suture by first coating a polyvinyl ester solution onto the surface of the suture and then removing the solvent from the coated suture.

4 Claims, No Drawings

SUTURE COATED WITH A POLYVINYL ESTER

BACKGROUND OF THE INVENTION

This invention relates to coated surgical sutures. More specifically, it relates to sutures coated with a vinyl polymer and to a method for improving the knot tiedown performance of a surgical suture.

Surgical sutures often require a surface coating to improve one or more of their performance properties. For example, a multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture, so it passes easily and smoothly through tissue during operative procedures. A monofilament suture may also require a surface coating to reduce the stiff feel of the suture and to increase its pliability.

In response to the need for suitable coatings for surgical sutures, numerous patents have disclosed potential coating compositions. U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,105,034 discloses a multifilament suture coating of a poly(alkylene oxalate), e.g. poly(hexamethylene oxalate). Although the coating compositions disclosed in these patents exhibit excellent handling characteristics and enhance many of the properties of the coated suture, the knot integrity of the coated suture diminishes slightly.

U.S. Pat. No. 3,527,650 discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although PTFE acts as an excellent lubricant to decrease the roughness of multifilament sutures, it has a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application. U.S. Pat. No. 4,043,344 discloses a PLURONICS ethylene oxide/propylene oxide copolymer coating for nonabsorbable surgical sutures. Unfortunately, these copolymer coatings lose their lubricity during wet tiedown evaluations.

In view of the deficiencies with the potential candidates for suture coatings, it would be desirable to develop a coating for a suture that can be applied using conventional techniques, that increases the tactile smoothness of the coated suture without sacrificing its physical properties, and that does not adversely affect the knot integrity of the suture.

SUMMARY OF THE INVENTION

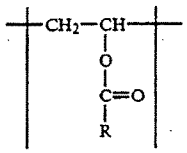
In one aspect, the invention is a suture having its surface coated with an amount of at least one polyvinyl ester effective to improve its knot tiedown performance relative to the knot tiedown performance of the uncoated suture.

In another aspect, the invention is a method of improving the knot tiedown performance of a suture. This method comprises the steps of coating the surface of the suture with an effective amount of a solution of at least one polyvinyl ester in an organic solvent, and then removing the solvent from the coated suture.

The polyvinyl ester coating of this invention can be applied to the surface of a suture using conventional techniques. The knot tiedown performance of the coated suture, which is an indication of its tactile smoothness, dramatically improves without sacrificing the tensile properties of the coated suture. Surprisingly, these improvements in properties are acheived without adversely affecting the knot security of the coated suture.

DETAILED DESCRIPTION OF THE INVENTION

Polyvinyl (PV) esters within the scope of this invention are known and can be prepared by conventional techniques, for example, by polymerizing a vinyl ester monomer using a free radical initiation process. Preferably, the PV ester is represented by repeating units of the formula:



wherein R is C_{6-30} straight or branched alkyl.

If the alkyl group of the formula above were to have less than 10 carbons, then the ester would not typically exhibit good coating properties. If the alkyl group were to have greater than 30 carbons, then the availability and purity of the ester would typically not be desirable for coating applications. Preferably, R is C_{14-18} straight alkyl. The most preferred PV ester is polyvinyl stearate.

The amount of PV ester coated onto the surface of the suture to improve knot tiedown performance will generally depend on the molecular weight of the PV ester and can readily be determined empirically. In most instances, the required amount of PV ester decreases as its molecular weight increases. Advantageously, the amount of PV ester coated onto the suture ranges from about 0.3 to about 20, preferably from about 0.5 to about 15 percent of the weight of the coated suture. Generally, amounts greater than 20 weight percent may compromise the knot security of the coated suture and amounts below 0.3 weight percent may fail to achieve any significant improvement in suture properties. The suture can be coated with not only one PV ester, but also a mixture of 2 or more PV esters, if desired. Preferably, the suture is coated with one PV ester.

The PV ester coatings of this invention are typically characterized by a weight average molecular weight as determined by gel permeation chromatography ranging from about 50,000 to about 2,000,000, preferably from about 100,000 to about 1,000,000, and most perferably from about 200,000 to about 500,000. A PV ester with molecular weight below 50,000 may fail to significantly improve the knot tiedown of a coated suture, and a PV ester with molecular weight above 2,000,000 may increase the stiffness of the coated suture.

Sutures within the scope of this invention can be of any type used or contemplated for operative procedures. The suture can be synthetic or natural, absorbable or nonabsorbable, or a monofilament or multifilament in a braided, twisted or covered form. In addition, the sutures can be attached to one or more needles, if desired. Examples of absorbable monofilament sutures include natural sutures such as surgical gut and collagen, and synthetic sutures such as homopolymers and copolymers of p-dioxanone. Examples of absorbable multifilament sutures include sutures prepared from fiber-forming polymers of one or more lactones, e.g. VICRYL ® poly(lactide-co-glycolide) multifilament

suture. Examples of nonabsorbable monofilament and multifilament sutures include nylon, polypropylene, steel, polyvinylidene fluoride, linen, cotton, silk, and polyesters such as polyethylene terephthalate (PET). The preferred sutures are nonabsorbable, multifilament sutures, preferably polyester sutures. The most preferred suture is PET.

The organic solvent for the PV ester coating of this invention is advantageously a solvent which has a normal boiling point no greater than 120° C. Examples of suitable organic solvents include but are not limited to chlorinated aliphatic solvents such as 1,1,2-trichloroethane and aromatic solvents such as toluene.

The coating can easily be prepared by simply dissolving the PV ester into the appropriate organic solvent. The concentration of the ester in solution will, of course, depend on the amount of PV ester desirably coated onto the surface of the suture, but generally should range from about 3 to about 20, preferably from about 5 to about 15 weight percent.

Once a solution of the PV ester is prepared, a suture can be coated using conventional coating techniques, e.g. dipping, spraying, etc. After the coating is applied, the solvent can be removed by drying in air, or by other techniques well known in the art, for example, removing the solvent at an elevated temPerature under vacuum.

The organic solvent and the preparation of a coating solution for application is normally required for coating multifilament sutures. However, an alternative approach is feasible for coating monofilament sutures without requiring the preparation of coating solution. If a synthetic monofilament suture is to be coated, then the fiber-forming polymer from which the suture is derived could be coextruded with a suitably low molecular weight PV ester so that the ester could exude to the surface of the fiber during extrusion to increase its tactile smoothness. Such methods have been demonstrated to enhance the lubricity and knotting characteristics of the fiber-forming polymer.

The PV ester in preferred embodiments of this invention is an essentially nonabsorbable, water insoluble, waxy solid. However, the ester can be modified or additives can be incorporated into the coating composition to tailor coating properties for specific applications. For example, the ester can be made water soluble by copolymerizing the ester with a polyvinyl alcohol and/or polyvinyl pyrrolidone. Alternatively, a vinyl alcohol ester could be copolymerized with vinyl alcohol and/or vinyl pyrrolidone. A bioabsorbable ester especially suited for absorbable sutures can be prepared by first functionalizing a low molecular weight PV ester, and then copolymerizing it with one or more lactones, e.g. glycolide, ϵ-Caprolactone, lactide, p-dioxanone, and the like. Similarly, silicone lubricating agents such as polydimethylsiloxane resins and elastomers, as well as other known polymeric coatings such as homopolymers and copolymers of p-dioxanone and PLURONICS ethylene oxide/propylene oxide copolymers, can be added to the coating composition to modify or enhance the final properties of the coated suture. All of these embodiments, as well as similar embodiments to modify or enhance the coated suture properties, are well within the scope of the claimed invention.

Although the PV ester has been described as a coating for surgical sutures, noncoating applications can be readily envisioned. For example, the PV ester may be used as a slip agent in thermo-dye transfer processes, as an elastomeric component for polyester molding compounds for bumpers and dashboards of automobiles, as a component in tissue adhesives for dentistry and surgery and as a component in jet printing ink applications.

The following example illustrates but is in no way intended to limit the scope of the claimed invention. In the example, the tensile properties, tiedown roughness and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The tiedown roughness is a measure of the knot tiedown performance. It provides an indication of the force required to slide a knot down a suture, and it is determined generally according to the procedure described in U.S. Pat. No. 3,942,532. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping.

EXAMPLE

For each of three runs, a solution of polyvinyl stearate with a weight average molecular weight of 239,000 and a melting temperature of 48° C. in toluene is prepared. A size 2/0 (USP standard) MERSILENE® PET braided multifilament suture is coated at room temperature with the coating solution using conventional laboratory coating equipment, and the coated suture is subsequently dried in air at 110° F. to remove the toluene. Table 1 compares the tensile and tiedown roughness properties and the knot security characteristics for each of the three runs with an uncoated MERSILENE PET braided multifilament suture.

TABLE 1

PROPERTIES OF POLYESTER SUTURE COATED WITH POLYVINYL STEARATE (PVS)

	PVS COATING CONCENTRATION IN TOLUENE, WT. PERCENT			UNCOATED SUTURE
	5.15	8.10	12.15	CONTROL
Percent Solids[1], wt.	0.97	1.74	5.20	—
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Dry Tiedown Roughness, gms.	140.4	127.8	118.6	355.5
Wet Tiedown Roughness, gms.	126.2	135.4	137.1	249.2
Wet Knot Security	4	4	4	4
Dry Knot Tensile Strength, psi	52,567	51,973	50,232	52,458
Wet Knot Tensile Strength, psi	53,971	54,452	48,832	56,794
Dry Straight Tensile Strength, psi	94,882	94,235	91,994	102,946
Percent Elongation	14.70	15.00	16.30	16.27

[1]Determined by measuring the difference in weight between the coated and uncoated suture.
[2]Wet properties are determined after soaking the suture in water at 25° C. for at least 24 hours.

The results indicate that the polyester suture coated with a varying amount of polyvinyl stearate exhibits significantly improved dry and wet tiedown roughness relative to that of the uncoated suture. The improved roughness is achieved without sacrificing knot security or the tensile properties of the uncoated suture. Gener-

ally, a wet tiedown roughness of less than 200 grams, preferably less than 150 grams, for the coated sutures of this invention can be readily obtained.

Similar outstanding results can be obtained with other PV ester coatings within the scope of the claimed invention.

We claim:

1. A method of improving the knot tiedown performance of a suture comprising the steps of:

a) coating an outer surface of the suture with a solution of at least one homopolymer of a vinyl ester monomer in an organic solvent, and then

b) removing the solvent from the coated suture so as to coat the suture with an amount of the homopolymer from 0.3 to 20 percent of the weight of the coated suture.

2. The method of claim 1 wherein the solution of the homopolymer of a vinyl ester monomer is a solution of between 0.5 to 15 weight percent of the homopolymer in toluene.

3. The method of claim 2 wherein the solvent is removed by drying the coated surface in air.

4. The method of claim 3 wherein the coated suture is dried at a temperature greater than room temperature.

* * * * *

Exhibit 8

United States Patent [19]

Mattei et al.

[11] **Patent Number: 4,532,929**

[45] **Date of Patent: Aug. 6, 1985**

[54] **DRY COATING OF SURGICAL FILAMENTS**

[75] Inventors: **Frank V. Mattei**, Piscataway; **Donald W. Regula**, Flagtown, both of N.J.

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **633,759**

[22] Filed: **Jul. 23, 1984**

[51] **Int. Cl.**[3] **A61L 17/00**

[52] **U.S. Cl.** **128/335.5**; 427/2; 428/263; 428/378

[58] **Field of Search** 128/335, 335.5; 428/263, 378; 427/2

[56] References Cited

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4,105,034	8/1978	Shalaby et al.	128/335.5
4,201,216	5/1980	Mattei	128/335.5

Primary Examiner—Jacqueline V. Howard
Attorney, Agent, or Firm—Charles J. Metz

[57] **ABSTRACT**

Braided or monofilament surgical filaments are coated with dry, powdered, substantially water-insoluble, absorbable salt of a C_6 or higher fatty acid, such as calcium stearate.

20 Claims, No Drawings

DRY COATING OF SURGICAL FILAMENTS

TECHNICAL FIELD

This invention relates to a dry, absorbable composition useful as a coating and lubricating finish for surgical filaments, and to a method for using said composition. More particularly, this invention relates to a means for improving the tie-down properties of absorbable and non-absorbable monofilament surgical filaments as well as multifilament surgical filaments by coating them with a dry, absorbable lubricating composition.

BACKGROUND ART

Suture materials and other surgical filaments such as ligatures are generally classified as either absorbable or non-absorbable, with each type of suture material being preferred for certain applications. Absorbable suture materials are preferred for internal wound repair in which the sewn tissues will hold together without suture reinforcement after healing and in which a nonabsorbed suture may promote tissue irritation or other adverse bodily reaction over an extended period of time. Suture materials are considered to be absorbable if they disappear from the sewn tissue within about a year after surgery, but many absorbable suture materials disappear within shorter periods.

The earliest available absorbable suture materials were surgical gut and extruded collagenous materials. More recently, absorbable sutures derived from synthetic polymers have been developed which are strong, dimensionally uniform, and storage stable in the dry state. Typical of such polymers are lactide homopolymers and copolymers of lactide and glycolide such as those disclosed in U.S. Pat. No. 3,636,956, and glycolide homopolymers such as those disclosed in U.S. Pat. No. 3,565,869.

Monofilament synthetic absorbable suture materials are generally stiffer than their multifilament surgical gut or collagen counterparts, and synthetic absorbable sutures are therefore usually employed in a multifilament, braided construction in order to provide the suture with the desired degree of softness and flexibility. Such multifilament sutures exhibit a certain degree of undesirable roughness or "grabbiness" in what has been termed their "tie-down" performance, i.e., the ease or difficulty of sliding a knot down the suture into place, or the ease of snugging a square knot in place.

Multifilament nonabsorbable sutures such as braided sutures of polyethylene terephthalate, for example, can be improved with respect to tie-down performance by coating the external surface of the suture with solid particles of polytetrafluorethylene and a binder resin as disclosed in U.S. Pat. No. 3,527,650. This procedure, however, is undesirable as applied to absorbable sutures because polytetrafluoroethylene is nonabsorbable and sutures coated therewith would leave a polymer residue in the sewn tissue, after the suture had been absorbed.

Multifilament, nonabsorbable sutures can also be improved with respect to tie-down performance by coating them with a linear polyester having a molecular weight between about 1,000 and about 15,000 and at least two carbon atoms between the ester linkages in the polymer chain as disclosed in U.S. Pat. No. 3,942,532.

U.S. Pat. No. 3,297,033 discloses that the synthetic absorbable sutures described therein may be coated with conventional suture coating materials such as a silicone or beeswax in order to modify the handling or absorption rate of the sutures. These coating materials are not readily absorbable, however, and will accordingly leave an undesirable residue in the tissue after the suture itself is absorbed.

Many other compounds have been proposed as treating agents to improve the lubricity and handling of both natural and synthetic filaments. U.S. Pat. No. 3,896,841 describes the treatment of collagen sutures with a hygroscopic agent and lubricant to provide a suture which permanently retains at least 10 percent by weight moisture. Sutures so treated are reported to have increased suppleness and reduced drag when passing through tissue. Fatty compounds and derivatives of fatty compounds are suggested as useful lubricating agents for such collagen sutures.

U.S. Pat. No. 3,982,543 discloses that multifilament, absorbable sutures may be lubricated/coated with a copolymer of lactide and glycolide in order to reduce the capillarity of the suture, and that sutures so treated are reported to have improved run down.

Because of the nature of surgical procedures, sutures and ligatures are generally exposed to body fluids or passes one or more times through moist tissue before tying, and an effective suture coating composition ideally provides wet tie-down characteristics substantially equivalent to those of the dry suture.

U.S. Pat. No. 4,143,423 discloses coating surgical applicances with a gloving agent or lubricant comprising a water soluble nontoxic alkali metal compound such as sodium bicarbonate. The compound may be coated as a powder by dusting or from an aqueous solution. Water soluble compounds would not, however, be suitable as lubricants for surgical sutures due to the nature of surgical procedures. Thus, the lubricant powders would be dissolved prematurely.

U.S. Pat. No. 4,201,216, issued May 6, 1980, to Frank V. Mattei, discloses as a coating for sutures, particularly synthetic absorbable multifilament sutures, an absorbable composition comprising a film-forming polymer and a substantially water-insoluble salt of a C_6 or a higher fatty acid. The coating is preferably applied to the suture from a solvent solution to provide a final coating add-on of from about 2 to 10 percent by weight of the sutures. In accordance with the teachings of said U.S. Pat. No. 4,201,216, the film-forming polymer is preferably a copolymer of lactide and glycolide, while the fatty acid salt is preferably a calcium salt of a C_6 to C_{22} fatty acid. The ratio of polymer to fatty acid salt in the coating composition may be within the range of about 1:4 to 4:1 parts by weight. The coating is wholly absorbable and is particularly useful for improving the dry and wet tie-down smoothness of braided sutures prepared from homopolymers and copolymers of lactide and glycolide, and other absorbable polymers. The patent discloses that where the compositions of the suture and the film former are identical, and in other instances where the suture material may be subject to some surface dissolution and/or surface swelling or softening by reason of the action of the film former solvent thereon, there may be a gradual transition between the substrate composition and the coating composition rather than a sharp interface between them. There may also be some weakening of the suture accompanying the application of such coating compositions.

It is an object of this invention to provide an improved method for coating monofilament sutures, as

well as multi-filament sutures of braided, twisted or covered construction, with a coating that improves the tie-down properties of such monofilament or multifilament sutures. It is a further object of this invention to provide a wholly absorbable coated synthetic monofilament or multifilament suture having improved and substantially equal dry and wet knot tie-down properties. It is yet a further object of this invention to provide such a wholly absorbable coated synthetic monofilament or multifilament suture having improved tie-down properties at least as desirable as those of sutures prepared in accordance with the teaching of U.S. Pat. No. 4,201,216, but having a substantially lower coating weight than that of the sutures of said U.S. Pat. No. 4,201,216, thus tie-down is improved by the minimal application of a safe material, such application being accomplished without using any organic solvents. The appearance and other esthetic attributes of the suture are only minimally affected, if at all, by the low level of add-on of the dry lubricating composition of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention, there is provided as a coating for surgical filaments such as sutures, and ligatures, particularly synthetic absorbable monofilament surgical filaments, an absorbable composition comprising a dry, finely powdered, substantially water insoluble salt of a C_6 or higher fatty acid. The coating may be applied on continuous lengths of monofilament or braid, using a series of powdered soft brushes followed by clean, soft wiping brushes to remove excess coating powder, or using other powder coating techniques that are known to the art, to provide a final coating add-on of below about 0.25 percent, and preferably below about 0.15 percent, by weight of the filament. The coating may also be applied to the filament manually by pulling the filament through fingers that had been powdered with the coating salt, e.g., calcium stearate, followed by pulling several times through clean fingers to remove any visible signs of the coating powder.

The fatty acid salt is preferably a calcium salt of a C_6 to C_{22} fatty acid. The coating is particularly useful for improving the dry and wet tie-down smoothness of monofilament sutures, such as those prepared from homopolymers and copolymers of p-dioxanone, polyolefins such as polypropylene, certain polyesters, and the like, as well as braided sutures prepared from homopolymers and copolymers of lactide or glycolide and other absorbable polymers, polyethylene terephthalate, silk, and the like.

The fatty acid salts useful in the coating powder compositions of the invention include the calcium, magnesium, barium, aluminum, and zinc salts of C_6 and higher fatty acids, particularly those having from about 12 to 22 carbon atoms, and mixtures thereof. The calcium salts of stearic, palmitic and oleic acids are particularly preferred for use in the invention. Mixtures of these salts may offer advantages in certain applications.

The amount of coating composition applied to the suture, or the coating add-on, will vary depending upon the construction of the suture, e.g., the number of filaments and tightness of braid or twist. In general, the coating composition applied to a suture will constitute up to about 0.25 percent by weight of the coated suture, and preferably up to about 0.15 percent by weight of the suture. As a practical matter, and for reasons of economy and general performance, it is generally preferred to apply the minimum amount of coating composition consistent with good tie-down performance, and this level of add-on is readily determined experimentally for any particular suture-coating system. Usually, the add-on will be at least about 0.02 weight percent, based on suture weight.

The improvement in tie-down properties imparted to sutures and ligatures may be determined semiquantitatively and subjectively by comparing the tie-down smoothness of coated and uncoated filaments during the act of tying down a single throw knot. Such comparisons are preferably made on both wet and dry filaments since many filaments materials have different tie-down properties when tested wet or dry. Tie-down roughness is graded from 0 to 10, with 0 being comparable to a rough filament and 10 indicating no detectable roughness.

Tie-down properties are evaluated dry after the strands of suture or ligature have been conditioned for at least 2 days in a vacuum drying oven at room temperature and 100 microns absolute pressure, and wet after being immersed in water at 25° C. for 1 minute. Values above 4 are considered acceptable, while values of 7 or higher are comparable to conventional silicone coated silk and are considered fully satisfactory.

The tie-down roughness test is carried out as follows:

The calibration standards for the test are uncoated poly(glycolide-co-lactide) braid, size 2/0, which is arbitrarily assigned a 0 rating, and size 2/0 braided poly(ethylene terephthalate) having a coating of polytetrafluoroethylene, which is assigned a 10 rating. A 24–36 inch strand of the material being tested is looped under a stationary bar, and a single throw know (overhand knot) is formed between the two free ends, near the ends. The two ends are grasped firmly in the hands and the ends are arranged so that the knot has its loops evenly spread out. Using 1–2 pounds of tension, the knot is caused to slide down at a moderate rate, with an even pull, until it comes to rest on the bar. After calibrating the strands for some 10–15 minutes with the two standards, the smoothness of tie-down is judged for the test samples, using the 0–10 scale. Usually, some 3–5 tie-downs are done on each strand, and about 4 strands are done per sample. For wet tie-down, the test is carried out immediately upon removal from the water. Only about 3 to 4 wet tie-downs are done on each strand, since the strand begins to dry out immediately upon removal from the water, and after 3 or 4 tests, is no longer wet. An average is taken of all the evaluations. While the test is subjective, and obviously operator-dependent, experiences has shown that different persons carrying out the test will get about the same results (i.e., the trends and differences between samples will be the same), even though the specific numbers obtained may not be exactly the same.

The following examples are provided to further illustrate and demonstrate the method and product of the invention. Unless otherwise stated, all parts and percentages are by weight.

EXAMPLE 1

Dry, powdered (100 percent smaller than 21 microns, 50 percent smaller than 8.5 microns) calcium stearate (in the form of a commercial food grade product consisting of about $\frac{1}{3}$ C_{16} and $\frac{2}{3}$ C_{18} fatty acid, with small amounts of C_{14} and C_{22} fatty acids) was applied as follows to size

1 dyed poly-p-dioxanone monofilament which had been scoured in acetone for three hours and then dried. The operator's fingers were powdered with the calcium stearate and the strands then individually pulled through the fingers 4–8 times so as to obtain a thorough and intimate coating. After removing the stearate from the fingers, the strands were pulled through clean fingers several more times to remove any visible signs of stearate.

EXAMPLE 2

The foregoing procedure was repeated using the monofilaments and fatty acid salt coating powders identified in Table I. The tie-down properties of the strands were then evaluated using the heretofore described semi-quantitative smoothness-of-tie-down tests, with the results set forth in Table I. The sterilized samples were sterilized either by ethylene oxide (EO) or by gamma irradiation from a cobalt-60 source.

TABLE I

Monofilament		% Add-on, 10 six foot strands	Smoothness of Tie-Down Ratings Based on 0–10 Subjective Scale					
			Dry			Wet		
			Unsterilized/Sterilized			Unsterilized/Sterilized		
Size 0, dyed poly-p-dioxanone monofilament	Uncoated control		3.5	4	(EO)	7.5	7.5	(EO)
Size 0, dyed poly-p-dioxanone monofilament	Calcium stearate	0.041	10	10	"	10	10	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium palmitate		10	9.5	"	9.5	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium laurate		10	10	"	10	10	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium oleate		3	3	"	8	8	"
Size 0, dyed poly-p-dioxanone monofilament	Calcium undecylenate		10	10	"	9.5	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Zinc stearate	0.15	9	9.5	"	9.5	9	"
Size 0, dyed poly-p-dioxanone monofilament	Magnesium stearate		10	10	"	9	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Magnesium myristate		9.5	9.5	"	9.5	9.5	"
Size 0, dyed poly-p-dioxanone monofilament	Zinc undecylate		10	10	"	9.5	10	"
Size 0, dyed poly[tetramethylene terephthalate-CO—(2-octadecenyl) succinate] monofilament (U.S. Pat. No. 4,388,296)	Uncoated control		2	1.5	(COBALT)	2	2	(COBALT)
	Calcium stearate		9	8	"	9	9	"
	Calcium palmitate		8	8	"	9	8.5	"
	Calcium laurate		6	5.5	"	2.5	4	"
	Zinc stearate		8.5	8.5	"	8.5	9	"
Size 0 Dyed Polypropylene monofilament	Uncoated control		2	1.5	(EO)	2	2	(EO)
Size 0 Dyed Polypropylene monofilament	Calcium stearate	0.06	9	9	"	9.5	9.5	"
Size 0 Dyed Polypropylene monofilament	Calcium palmitate		9	9	"	9	9	"
Size 0 Dyed Polypropylene monofilament	Calcium laurate		9.5	9.5	"	9.5	9	"
Size 0 Dyed Polypropylene monofilament	Zinc stearate	0.126	9.5	9.5	"	9	9	"
Size 2/0 scoured nylon[1] monofilament	Uncoated Control		6.5	—		7	—	
	Calcium stearate	—	10	—		9.5	—	

[1]Soaked in acetone for 3 hours at room temperature.

As is apparent from the above results, the dry coating of the invention is effective for improving the tie-down characteristics of a variety of surgical filaments such as sutures and ligatures using various salts of fatty acids. In the tests reported in Table I, only the calcium oleate coating of the poly-(p-dioxanone) monofilament suture showed no improvement in the dry test. Even this suture showed slight improvement in the wet tie-down test, although the results were not as good as for the other salts.

It may be readily appreciated that the coating may be used with good results on absorbable monofilament and multifilament sutures and ligatures as well as on nonabsorbable monofilament and multifilament sutures and ligatures.

Nonabsorbable sutures and ligatures such as cotton, linen, silk, polypropylene, and polyester are sometimes coated with nonabsorbable compositions. Polyolefins are usually of monofilament construction while cotton, linen, silk, and polyester are usually of braided, twisted, or covered multifilament construction. While there is usually no requirement that coatings on such sutures be absorbable, the composition of the invention may, nevertheless, be used as a finish for nonabsorbable sutures if desired. The only suture material that has been tried and found not to be improved by the invention is unscoured nylon monofilament. That is because unscoured nylon already has such good tie-down properties that any improvement that might be imparted by the invention is not detectable by the semi-quantitative subjective test used.

EXAMPLE 3

Twenty strands of size 0 undyed polyester (polyethylene terephthalate) braid, in three-foot lengths, were coated with dry calcium stearate powder by the procedure described in Example 1, above. The add-on level for the twenty strands was 1.5 weight percent (this was probably much higher than the add-on would be in a

commercial process, with a more efficient cleaning operation after the coating). Wet tie-down was 8½ (average of 4 strands), while the dry tie-down was 9 (average of 4 strands), using the same test for smoothness of tie-down described above. The uncoated controls were rated at 1 for both dry and wet. The appearance of the coated strands was excellent; they appeared to the naked eye to be uncoated.

What is claimed is:

1. A synthetic surgical filament having improved and substantially equal dry and wet tie-down properties, said surgical filament having been coated with from about 0.02 to 0.25 percent by weight of a composition consisting essentially of a dry, powdered, substantially water-insoluble, absorbable salt of a C_6 or higher fatty acid.

2. A surgical filament of claim 1, wherein said higher fatty acid is selected from the group consisting of C_{12} to C_{22} fatty acids and mixtures thereof.

3. A surgical filament of claim 1, wherein the fatty acid salt is a salt of calcium, magnesium, barium, aluminum, or zinc.

4. A surgical filament of claim 2, wherein the fatty acid salt is a salt of calcium or magnesium.

5. A surgical filament of claim 4, wherein the fatty acid comprises a mixture of stearic and palmitic acid.

6. A surgical filament of claim 5, wherein the fatty acid salt comprises a mixture of calcium palmitate and calcium stearate.

7. A surgical filament of claim 1, coated with from about 0.02 to 0.15 percent of the said mixture.

8. A surgical filament of claim 1, which is comprised of homopolymers or copolymers of lactide or glycolide.

9. A surgical filament of claim 8, wherein said surgical filament is comprised of a copolymer of 10 weight percent lactide and 90 weight percent glycolide.

10. A surgical filament of claim 9, which is a braided multifilament suture or ligature.

11. A surgical filament of claim 1, which comprises a homopolymer or a copolymer of p-dioxanone.

12. A surgical filament of claim 1, which is a monofilament suture or ligature.

13. A surgical filament of claim 11, which is a monofilament suture or ligature.

14. A surgical filament of claim 1 which is composed of a polymer selected from the group consisting of the polyolefins and the polyesters.

15. A method for imparting improving and substantially equal dry and wet tiedown properties to a surgical filament which comprises applying to the surface of said surgical filament in the form of a dry powder a water-insoluble, absorbable salt of a C_6 or higher fatty acid, and thereafter removing from the surface of said surgical filament excess said powder by rubbing said surface in intimate contact with a relatively powder free, nonabrasive surface until no powder is visible to the naked eye on said surgical filament surface.

16. The method of claim 15, wherein the fatty acid salt is the salt of calcium, magnesium, barium, aluminum, or zinc.

17. The method of claim 16, wherein said higher fatty acid is selected from the group consisting of C_{12} to C_{22} fatty acids and mixtures thereof.

18. The method of claim 15, wherein said surgical filament is an absorbable synthetic polymer selected from the group consisting of homopolymers and copolymers of lactide or glycolide.

19. The method of claim 15, wherein said surgical filament is a nonabsorbable synthetic polymer selected from the group consisting of the polyolefins and the polyesters.

20. The method of claim 16 wherein said surgical filament is a homopolymer or a copolymer of p-dioxanone.

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Exhibit 9

FiberWire™

IMPORTANT PRODUCT INFORMATION
WICHTIGE PRODUKTINFORMATION
NOTICE D'UTILISATION IMPORTANTE
IMPORTANTI INFORMAZIONI PER L'USO
INSTRUCCIONES IMPORTANTES PARA EL USO

CE 0086

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Arthrex®

DFU-0065
Rev. 6

ENGLISH

Description:
Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The Arthrex FiberWire may also be sold with needles attached (swaged) to the ends in a variety of sizes. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue. The Arthrex FiberWire is available non-dyed (white) or dyed and meets or exceeds U.S.P. and European standards (except for diameter).

Indications:
Arthrex FiberWire is indicated for use in soft tissue approximation and or ligation. FiberWire is not for use in cardiac indications.

Actions:
Arthrex FiberWire, when tested per ISO/DIS 10993, *Biological Evaluation of Medical Devices-Part 10: Tests for Irritations and Sensitization*, had no reactions of allergic or sensitive nature. The dyed suture and coating are pharmacologically inactive.

Arthrex FiberWire is not absorbed, but may become encapsulated in the surrounding connective tissues. The Arthrex FiberWire is not known to have significant change in tensile strength *in vivo*.

Contraindications:
None known

Warnings:
Do not re-sterilize. Once open, discard unused suture. Do not expose to heat.

Users should be familiar with surgical procedures and techniques involving non-absorbable sutures before employing Arthrex FiberWire for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formations. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

Precautions:
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.

Assure that all knots have been secured using accepted surgical knot tying techniques. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon. The use of additional throws may be particularly appropriate when knotting monofilaments. Care should be taken to prevent damage to surrounding tissue or user puncture due to improper handling of the needlepoint.

Do not grasp the needle at the point or swage, to avoid damage to these areas. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Discard used needles in "sharps" containers.

Adverse Reactions:
Adverse reactions have not been noted with the Arthrex FiberWire product in animal testing. Common non-absorbable suture reactions may include wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, enhanced bacterial infectivity, minimal acute inflammatory tissue reaction, pain, edema, and erythema at the wound site. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of bloodborne pathogens.

Sterilization:
Arthrex FiberWire suture is supplied sterile.
Method of sterilization - EO
Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused sutures.

Storage Conditions:
Store below 25°C, away from moisture and direct heat. Do not use after expiration date.

How Supplied:
The Arthrex FiberWire is available in several U.S.P. sizes (sutures meet U.S.P. standards for suture, except diameter). The suture is supplied sterile in pre-cut lengths and in some cases with swaged needles. The Arthrex FiberWire is available in non-dyed (white) or dyed colors. The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgical use. The coating acts as a lubricant for suture sliding, knot tying, and ease of passing suture through tissue.

SYMBOLS USED ON LABELING

Do not reuse	QTY Quantity
STERILE EO — Sterile unless the package is damaged or open. Method of sterilization - EO	
STERILE R — Sterile unless the package is damaged or open. Method of sterilization - gamma radiation	
LOT Lot number	See package insert
CE The product meets the essential requirements of Medical Device Directive 93/42 EEC.	
Use by - year & month	

DEUTSCH

Beschreibung:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Arthrex FiberWire ist unter Umständen auch mit an den Fadenenden befestigten (gesenkgeschmiedeten) Nadeln unterschiedlicher Größen erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe. Arthrex FiberWire ist ungefärbt (weiß) oder gefärbt erhältlich und entspricht oder übertrifft USP- und europäische Standards (mit Ausnahme des Durchmessers).

Anwendungsgebiete:
Arthrex FiberWire ist für Weichgewebeapproximation und/oder -ligation vorgesehen. FiberWire nicht für Kardio-Indikationen verwenden.

Funktionen:
Tests bei Arthrex FiberWire gemäß ISO/DIS 10993, *Biological Evaluation of Medical Devices - Part 10: Reiz- und Sensibilisierungstests* ergaben keine allergischen oder empfindlichen Reaktionen. Das gefärbte Nahtmaterial und die Beschichtung sind pharmakologisch inaktiv.

Arthrex FiberWire wird zwar nicht absorbiert, jedoch unter Umständen vom umgebenden Bindegewebe eingekapselt. Bei Arthrex FiberWire wurde *in vivo* keine signifikante Änderung der Zerreißfestigkeit festgestellt.

Gegenanzeigen:
Unbekannt

Warnhinweise:
Nicht resterilisieren. Unbenutztes Fadenmaterial nach dem Öffnen entsorgen. Von Hitze fernhalten.

Benutzer sollten vor dem Verschließen von Wunden mit Arthrex FiberWire mit den chirurgischen Prozeduren und Techniken vertraut sein, bei denen nicht-absorbierbarer Faden verwendet wird, da das Dehiszenzrisiko je nach Anwendungsstelle und verwendetem Fadenmaterial unterschiedlich ist.

Wie bei Fremdkörpern aller Art kann der längere Kontakt dieses oder jedes anderen Fadenmaterials mit Salzlösungen, (wie sie z.B. im Harn- und Gallentrakt vorhanden sind) zu Calculusbildung führen. Bei der Drainage und beim Schließen von infizierten oder kontaminierten Wunden sind die in der Chirurgie üblichen Praktiken zu beachten.

Vorsichtsmaßnahmen:
Bei der Handhabung dieses oder jedes anderen Fadenmaterials sorgfältig darauf achten, dass das Material nicht beschädigt wird. Schäden durch Zusammendrücken oder Abklemmen mit chirurgischen Instrumenten wie Zangen oder Nadelhaltern nach Möglichkeit vermeiden.

Sicherstellen, dass sämtliche Knoten gemäß den akzeptierten chirurgischen Knotenbildungstechniken sicher befestigt wurden. Voraussetzung für angemessene Knotenhaltbarkeit ist die Verwendung von flachen, quadratischen Schleifen mit zusätzlichen Verknotungen, je nach chirurgischer Situation und Erfahrung des Chirurgen. Besonders beim Verknoten von monofilen Fäden sind unter Umständen zusätzliche Verknotungen angebracht. Sorgfältig vorgehen, um Schäden am umgebenden Gewebe und Benutzerpunktierung durch falsche Handhabung der Nadelspitze zu vermeiden.

Die Nadel nicht an der Spitze oder am Gesenk festhalten, um eine Beschädigung dieser Bereiche zu vermeiden. Nadeln können durch Umformen an Stärke verlieren und gegen Verbiegen und Abbrechen weniger widerstandsfähig werden. Nadeln in entsprechend gekennzeichneten Behältern entsorgen.

Nebenwirkungen:
Bei Tierversuchen wurden bei der Verwendung von Arthrex FiberWire keine Nebenwirkungen festgestellt. Zu den bei nicht-absorbierbarem Faden üblichen Reaktionen zählen unter Umständen Dehiszenz, Calculusbildung in Harn- und Gallenwegen bei längerem Kontakt mit Salzlösungen (wie sie im Urin und in der Gallenflüssigkeit vorhanden sind), verstärkte Bakterienaffektion, minimale akute Gewebeentzündungen, Schmerzen, Ödeme und Erythema an der Wundstelle. Versehentliches Stechen mit kontaminierten chirurgischen Nadeln kann zur Übertragung von Blutpathogenen führen.

Sterilisation:
Arthrex FiberWire wird steril geliefert.
Sterilisationsmethode - EO.
Nicht resterilisieren. Bei beschädigter oder zuvor geöffneter Packung nicht verwenden. Offenes, unbenutztes Fadenmaterial entsorgen.

Lagerungsbedingungen:
Unter 25 °C trocken und fern von direkter Hitzeeinwirkung lagern. Nicht nach dem Verfallsdatum verwenden.

Lieferform:
Arthrex FiberWire ist in verschiedenen USP-Größen erhältlich (das Nahtmaterial entspricht den USP-Normen für Nahtmaterial, mit Ausnahme des Durchmessers). Das Fadenmaterial wird steril in vorgeschnittenen Längen und in manchen Fällen mit gesenkgeschmiedeten Nadeln geliefert. Arthrex FiberWire ist ungefärbt (weiß) und gefärbt erhältlich. Das Nahtmaterial besteht aus geflochtenen, sterilisierten und für den chirurgischen Gebrauch beschichteten Polyethylen und Polyesterfäden. Die Beschichtung fungiert als Fadengleitmittel und erleichtert die Knotenbildung und das Durchziehen des Fadens durch das Gewebe.

AUF DER VERPACKUNG VERWENDETE SYMBOLE

Nicht wiederverwenden!	QTY Quantität
STERILE EO — Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - EO	
STERILE R — Steril, solange die Verpackung ungeöffnet und unbeschädigt ist. Sterilisationsmethode - Bestrahlung	
LOT Chargenbezeichnung	Siehe Packungsbeilage
CE Das Produkt entspricht den grundlegenden Anforderungen der Richtlinie des Rates über Medizinprodukte 93/42/EWG.	
Verwendbar bis Jahr und Monat	

FRANÇAIS

Description:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture Arthrex FiberWire est également commercialisée avec des aiguilles serties de différentes tailles. Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou teintée, et elle est conforme aux normes européennes et normes U.S.P. (diamètre excepté).

Indications:
La suture Arthrex FiberWire est indiquée pour la ligature et le rapprochement des tissus mous. La suture Arthrex FiberWire n'est pas indiquée pour la chirurgie cardiaque.

Réactions:
Aucune réaction allergique ou sensible n'a été observée lors de la soumission de la suture Arthrex FiberWire au test exigé par la norme ISO/DIS 10993 / *Evaluation biologique des dispositifs médicaux, Partie 10 : Essais d'irritation et de sensibilisation.* La suture teintée et le traitement en surface de la suture sont pharmacologiquement inactifs.

La suture Arthrex FiberWire est non résorbable. Elle peut cependant être encapsulée par le tissu conjonctif. Selon les données disponibles, la résistance à la traction de la suture Arthrex FiberWire ne change pas de manière significative *in vivo*.

Contre-indications:
Aucune contre-indication connue.

Précautions d'emploi:
Ne pas stériliser à nouveau. Jeter toute suture non utilisée dont l'emballage a été ouvert. Ne pas exposer à la chaleur.

Tout praticien suturant une plaie avec la suture Arthrex FiberWire doit être familiarisé aux techniques chirurgicales recommandées pour les matériaux non résorbables, car le risque de déhiscence de la plaie varie selon le site de l'intervention et selon le type de suture employé.

Comme avec tout matériau exogène, un contact prolongé de cette suture ou de tout autre fil avec un fluide salin, comme ceux circulant dans les voies urinaires ou biliaires, peut conduire à la formation de calculs. Le praticien devra respecter les règles chirurgicales relatives au drainage et à la fermeture de plaies infectées ou contaminées.

Précautions d'emploi:
Comme avec toute autre suture, éviter d'abîmer le fil lors de sa manipulation. Ne pas écraser le fil avec des instruments chirurgicaux comme une pince ou un porte-aiguille.

Réaliser tous les nœuds conformément aux techniques chirurgicales en vigueur. Opter pour le nœud plat, qui garantit une bonne sécurité et qui est largement utilisé, avec boucles supplémentaires en fonction du cas chirurgical et de l'expérience du praticien. Si le fil est monofilament, prévoir des boucles supplémentaires pour les nœuds.

Bien contrôler la pointe de l'aiguille pour éviter de piquer les tissus environnants ou de blesser le praticien.

Ne pas saisir l'aiguille par sa pointe ou par son attache sur le fil pour éviter de l'endommager. Eviter de modifier la courbure des aiguilles pour ne pas réduire leur résistance à la déformation et à la rupture. Après usage, jeter les aiguilles dans un récipient spécial pour objets pointus et tranchants.

Effets indésirables:
Aucun effet indésirable particulier n'a été observé lors des tests du fil Arthrex FiberWire chez l'animal. Comme avec les autres fils de suture non résorbables, les réactions suivantes sont possibles : déhiscence de la plaie, formation de calculs dans les voies urinaires ou biliaires si contact prolongé avec des fluides salins comme l'urine ou la bile, infectivité bactérienne accrue, inflammation tissulaire minime, douleur, œdème et érythème au niveau de la plaie. Toute blessure avec une aiguille chirurgicale contaminée peut transmettre des germes pathogènes présents dans le sang.

Stérilisation:
La suture Arthrex FiberWire est livrée stérile.
Méthode de stérilisation : oxyde d'éthylène
Ne pas stériliser à nouveau. Ne pas utiliser si l'emballage est ouvert ou endommagé. Jeter les sutures non utilisées si leur emballage est ouvert.

Conditions de stockage:
Conserver à une température maximale de 25°C et à l'abri de l'humidité comme des sources de chaleur directes. Ne pas utiliser après la date d'expiration.

Présentation:
La suture Arthrex FiberWire existe en plusieurs tailles U.S.P. et elle est conforme aux normes U.S.P. s'appliquant aux sutures (diamètre excepté). La suture est livrée stérile en différentes longueurs précoupées. Elle est aussi disponible avec des aiguilles serties. La suture Arthrex FiberWire est disponible en blanc (non teinté) ou en couleurs (teinté). Cette suture se compose de fibres de polyéthylène et de fibres de polyester tressées, stérilisées et traitées en surface pour les applications chirurgicales. Ce revêtement joue le rôle de lubrifiant pour faciliter le glissement du fil, le serrage des nœuds et le passage du fil à travers les tissus.

SYMBOLES UTILISÉS SUR L'ÉTIQUETAGE

Ne pas réutiliser
QTY Quantité
STERILE EO Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - EO
STERILE R Produit stérile si l'emballage n'a pas été ouvert ou endommagé. Méthode de stérilisation - irradiation
LOT No. de lot
Consulter la notice accompagnant le produit
CE Ce produit est conforme aux exigences de la directive sur les dispositifs médicaux CEE 93/42.
À utiliser avant le (mois/année)

ITALIANO

Descrizione:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro). FiberWire Arthrex può essere venduto anche con aghi di varie dimensioni attaccati (saldati) alle estremità. La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto. FiberWire Arthrex è disponibile sia non tinto (bianco) che tinto e soddisfa o supera gli standard U.S.P. ed europei (non per diametro).

Indicazioni:
FiberWire Arthrex è indicato per l'approssimazione e/o la legatura dei tessuti molli. FiberWire non va utilizzato in interventi cardiaci.

Azioni:
FiberWire Arthrex, quando testato per ISO/DIS 10993, *Valutazione biologica dei dispositivi medici-Parte 10: I test per irritazioni e sensibilizzazione,* non hanno evidenziato reazioni allergiche o ipersensibilità. La sutura e il rivestimento tinti sono farmacologicamente inattivi.

FiberWire Arthrex non viene assorbito, ma può essere incapsulato nei tessuti connettivi circostanti. Non sono noti per FiberWire Arthrex cambiamenti significativi nella resistenza alla tensione *in-vivo*.

Controindicazioni:
Nessuna nota

Avvertenze:
Non risterilizzare. Una volta aperte, gettare le suture non utilizzate. Non esporre al calore.

Gli utenti devono conoscere bene le procedure e le tecniche chirurgiche relative alle suture non assorbibili prima di utilizzare FiberWire Arthrex per la chiusura delle ferite, in quanto il rischio di deiscenza della ferita può variare in base al sito di applicazione ed al materiale utilizzato per la sutura.

Come per qualsiasi corpo estraneo, il contatto prolungato di questa e qualsiasi altra sutura con soluzioni saline, come quelle presenti nel tratto urinario o biliare, può risultare nella formazione di calcoli. È necessario seguire una pratica chirurgica corretta per il drenaggio e la chiusura di ferite infette o contaminate.

Precauzioni:
Nel trattare questo o qualsiasi altro materiale per sutura, occorre fare attenzione ad evitare danni dovuti al maneggiamento. Evitare danni da schiacciamento o piegature dovuti all'applicazione di strumenti chirurgici, inclusi forcipi o porta-aghi.

Assicurarsi che tutti i nodi siano stati legati usando le tecniche chirurgiche di annodatura accettate. Una sicurezza adeguata del nodo richiede la tecnica chirurgica accettata di legature piatte e quadrate, nonché di ulteriori avvolgimenti in base al caso chirurgico e all'esperienza del chirurgo. L'uso di avvolgimenti aggiuntivi può essere particolarmente appropriato per l'annodamento di monofilamenti. Evitare di recare danni al tessuto circostante o alla puntura dovuti ad una manipolazione non corretta della punta dell'ago.

Non afferrare l'ago per la punta o dalla saldatura, onde evitare danni a queste aree. Il riadattamento degli aghi può indebolirli e renderli meno resistenti alle piegature ed alle rotture. Gettare gli aghi usati in contenitori per materiale «affilato».

Effetti Indesiderati:
Non si sono riscontrati effetti indesiderati con l'uso del prodotto FiberWire Arthrex nei test sugli animali. Le reazioni comuni alle suture non assorbibili possono includere la deiscenza della ferita, la formazione di calcoli nei tratti urinario e biliare dovuta al contatto prolungato con soluzioni saline come urina e bile, infettività batterica elevata, minima reazione del tessuto alle infiammazioni acute, dolore, edema ed eritema al sito della ferita. Il contatto involontario dell'ago con aghi chirurgici contaminati può risultare nella trasmissione di patogeni veicolati dal sangue.

Sterilizzazione:
La sutura FiberWire Arthrex viene fornita sterile.
Metodo di sterilizzazione - EO
Non risterilizzare. Non utilizzare se la confezione è aperta o danneggiata. Gettare le suture aperte non utilizzate.

Condizioni di conservazione:
Conservare al di sotto di 25°C, lontano da umidità e calore diretto. Non utilizzare dopo la data di scadenza.

Come si presenta:
FiberWire Arthrex è disponibile in molte misure U.S.P. (le suture soddisfano gli standard U.S.P. per sutura, tranne il diametro. La sutura viene fornita sterile in lunghezze pretagliate ed in alcuni casi con aghi saldati. FiberWire Arthrex è disponibile tinto o non tinto (bianco). La sutura consiste in maglie di fibre di polietilene e di poliestere sterilizzate e rivestite per uso chirurgico. Il rivestimento funge da lubrificante per lo scorrimento della sutura, la chiusura dei nodi e la facilità di passaggio della sutura attraverso il tessuto.

SIMBOLI USATI SULL'ETICHETTA

Monouso
QTY Quantità
STERILE EO Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - EO
STERILE R Il prodotto è sterile se la confezione non è aperta o danneggiata. Metodo di sterilizzazione - Raggi Gamma
LOT Numero di lotto
Fare riferimento all'inserto contenuto nella confezione
CE Il prodotto è conforme ai requisiti essenziali della Direttiva CEE 93/42 sui Dispositivi Medici.
Da usarsi entro anno e mese

ESPAÑOL

Descripción:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas de U.S.P. para suturas, excepto en el diámetro). También es posible encontrar la sutura FiberWire de Arthrex en diversos tamaños y con agujas incorporadas (enhebradas) en los extremos. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido. La sutura FiberWire de Arthrex viene en modelos sin teñir (blanca) o teñida y cumple o supera las normas de U.S.P. y Europa (excepto en el diámetro).

Indicaciones:
La sutura FiberWire de Arthrex está indicada para aplicaciones de aproximación y ligadura de tejido blando. La sutura FiberWire no está indicada para uso cardíaco.

Acciones:
Sutura FiberWire de Arthrex, sometida a prueba de acuerdo con la norma ISO/DIS 10993, *Evaluación Biológica de Dispositivos Médicos-Sección 10: En pruebas para detección de irritaciones y sensibilidad,* no hubo reacciones alérgicas ni de sensibilidad. La sutura teñida y el recubrimiento son inactivos farmacológicamente.

La sutura FiberWire de Arthrex no se absorbe, pero podría encapsularse en los tejidos conjuntivos adyacentes. La sutura FiberWire de Arthrex no presenta cambios significativos conocidos en cuanto a resistencia a la tracción *in vivo*.

Contraindicaciones:
Ninguna conocida

Advertencias:
No esterilizar de nuevo. Una vez abierto el paquete, desechar la sutura no utilizada. No exponer al calor.

Los usuarios deberán conocer los procedimientos quirúrgicos y las técnicas con suturas no absorbibles antes de utilizar FiberWire de Arthrex para cerrar heridas, ya que el riesgo de dehiscencia de las heridas varía según el sitio de aplicación y el material de sutura utilizado.

Al igual que ocurre con todo cuerpo extraño, el contacto prolongado de esta sutura, o de cualquier otro tipo de sutura, con soluciones salinas como las halladas en los tractos urinario o biliar, podría producir cálculos. Se deben usar métodos quirúrgicos aceptables en relación con el drenaje y cierre de heridas infectadas o contaminadas.

Precauciones:
Se debe tener cuidado al manipular este o cualquier otro material de sutura para evitar dañarlo. No utilice instrumentos quirúrgicos o de aplicación tales como fórceps o porta-agujas para evitar aplastar o plegar el material.

Cerciórese de que todos los nudos se hayan fijado por medio de técnicas aceptadas para nudos quirúrgicos. Para la fijación correcta de los nudos es necesario utilizar la técnica quirúrgica aceptada de nudos planos y cuadrados con lazadas adicionales, según lo requieran las condiciones quirúrgicas y la experiencia del cirujano. El uso de lazadas adicionales podría ser especialmente útil en la elaboración de nudos de monofilamentos. Debe tenerse cuidado para evitar daños al tejido adyacente o punciones producidas por el usuario al manipular incorrectamente la punta de la aguja.

No sujete la aguja por la punta ni por el ojo para evitar daños en esas partes. Si se modifica la forma de las agujas, éstas podrían perder su firmeza y ser menos resistentes a las curvaturas y el rompimiento. Deseche las agujas usadas en recipientes para objetos punzantes.

Reacciones adversas:
No se han detectado reacciones adversas del producto FiberWire de Arthrex en pruebas con animales. Entre las reacciones comunes de las suturas no absorbibles se encuentran: dehiscencia de las heridas, formación de cálculos en los tractos urinario y biliar en condiciones de contacto prolongado con soluciones salinas tales como la orina y la bilis, mayor propensión a infecciones bacterianas, reacción mínima inflamatoria aguda del tejido, dolor, edema y eritema en el sitio de la herida. El pinchazo accidental con agujas quirúrgicas usadas podría causar la transmisión de patógenos a través de la sangre.

Esterilización:
La sutura FiberWire de Arthrex se suministra estéril.
Método de esterilización - EO
No esterilizar de nuevo. No utilizar si el paquete llega abierto o dañado. Desechar las suturas abiertas que no se hayan utilizado.

Condiciones de almacenamiento:
Almacenar el producto por debajo de 25° C, alejado de la humedad y el calor directo. No utilizar después de la fecha de caducidad.

Presentación:
La sutura FiberWire de Arthrex viene en varios tamaños aprobados por U.S.P. (las suturas cumplen las normas U.S.P. para sutura, excepto en el diámetro). La sutura se suministra estéril en cortes de longitud predeterminada y en algunos casos con agujas enhebradas. La sutura FiberWire de Arthrex se encuentra disponible en modelos sin teñir (blanca) o teñida. La sutura está hecha de fibras de polietileno y poliéster trenzadas, esterilizadas y recubiertas para uso quirúrgico. El recubrimiento hace las veces de lubricante para deslizar la sutura, atar los nudos y facilitar el paso de la sutura a través del tejido.

SIMBOLOS UTILIZADOS EN LAS ETIQUETAS

No reutilizar
QTY Cantidad
STERILE EO Estéril mientras el envase no sea abierto o dañado. Método de esterilización - EO
STERILE R Estéril mientras el envase no sea abierto o dañado. Método de esterilización - irradiación
LOT Número de lote
Ver folleto en el interior del paquete
CE Este producto cumple con las normas básicas de la Directiva de productos médicos, 93/42 CEE.
Caduca - año y mes